EXHIBIT A

US005922021A

United States Patent [19]

Jang

[11] **Patent Number: 5,922,021**

[45] **Date of Patent: *Jul. 13, 1999**

[54] **INTRAVASCULAR STENT**

[76] Inventor: **G. David Jang**, 30725 Eastburn La., Redlands, Calif. 92374

[*] Notice: This patent is subject to a terminal disclaimer.

[21] Appl. No.: **08/845,657**

[22] Filed: **Apr. 25, 1997**

Related U.S. Application Data

[63] Continuation-in-part of application No. 08/824,142, Mar. 25, 1997, application No. 08/824,866, Mar. 25, 1997, and application No. 08/824,865, Mar. 25, 1997

[60] Provisional application No. 60/017,484, Apr. 26, 1996.

[51] **Int. Cl.**^{6} **A61F 2/06**

[52] **U.S. Cl.** **623/1**; 623/12

[58] **Field of Search** 623/1, 11, 12; 606/108, 191, 194, 195, 198

[56] **References Cited**

U.S. PATENT DOCUMENTS

5,102,417	4/1992	Palmaz .	
5,449,373	9/1995	Pinchasik et al.	606/198
5,591,197	1/1997	Orth et al.	606/194
5,593,442	1/1997	Klein	623/1
5,695,516	12/1997	Fischell et al.	606/194
5,697,971	12/1997	Fischell et al.	623/1
5,776,161	7/1998	Globerman .	
5,776,183	7/1998	Kanesake et al. .	
5,810,872	9/1998	Kanesaka et al.	623/1
5,824,059	10/1998	Wijay	623/1
5,836,964	11/1998	Richter et al.	623/1

FOREIGN PATENT DOCUMENTS

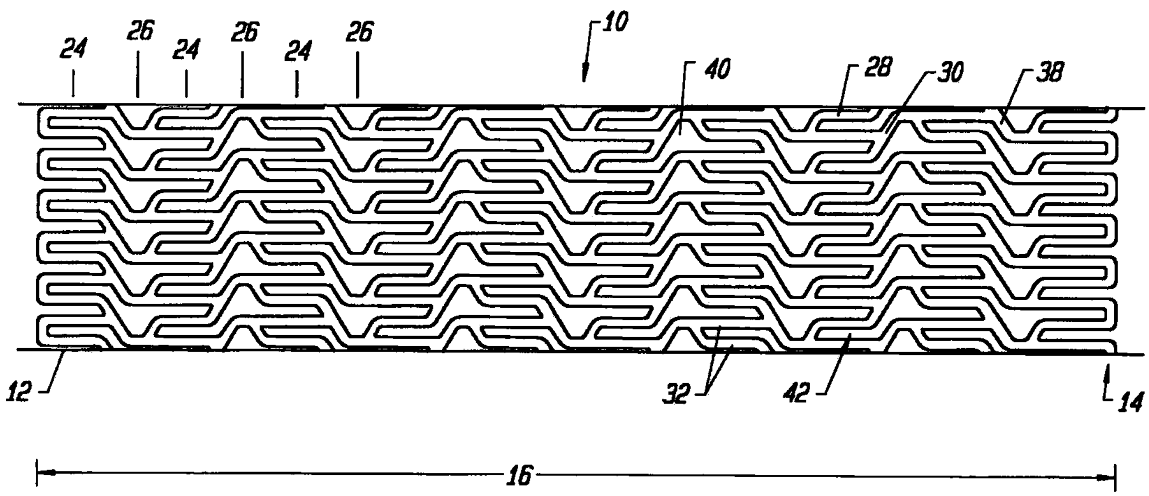
0 587 197 A1	3/1994	European Pat. Off.	A61F 2/04
606 165 A1	7/1994	European Pat. Off.	623/1
0 679 372 A2	11/1995	European Pat. Off.	A61B 19/00
0 709 067 A2	5/1996	European Pat. Off.	A61F 2/06
4303181 A1	8/1994	Germany	A61M 29/00
29608037 U1	8/1996	Germany	A61M 29/00
WO96/03029	2/1996	WIPO	A61F 2/02
WO96/26689	9/1996	WIPO	A61F 2/06
WO 97/40780	11/1997	WIPO .	
WO 97/40781	11/1997	WIPO .	

Primary Examiner—David H. Willse
Assistant Examiner—Tram A. Nguyen
Attorney, Agent, or Firm—Wilson Sonsini Goodrich & Rosati

[57] **ABSTRACT**

A stent in a non-expanded state has a first expansion strut pair consisting of a first expansion strut positioned adjacent to a second expansion strut and a joining strut which couples the first and second expansion struts at a distal end of the first expansion strut pair. A plurality of the first expansion strut pair form a first expansion column. A second expansion strut pair consists of a first expansion strut positioned adjacent to a second expansion strut and a joining strut couples the first and second expansion struts at a proximal end of the second expansion strut pair. A plurality of the second expansion strut pair form a second expansion column. A first connecting strut includes a first connecting strut proximal section, a first connecting strut distal section and a first connecting strut intermediate section. The first connecting strut proximal section is coupled to the distal end of the first expansion strut pair in the first expansion column and the first connecting strut distal section is coupled to the proximal end of the second expansion strut pair of the second expansion column. A plurality of the first connecting struts form a first connecting strut column that couples the first expansion column to the second expansion column. A length of the first connecting strut proximal section is equal to a length of the first connecting strut distal section, and a length of the first connecting strut intermediate section is greater than the length of the first connecting strut proximal and distal sections.

85 Claims, 27 Drawing Sheets



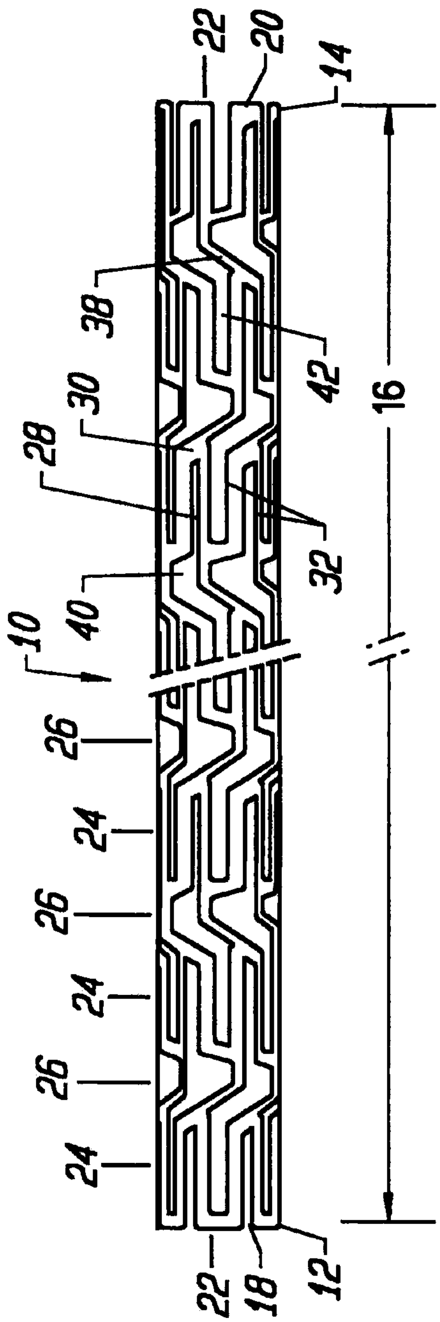


FIG. 1A

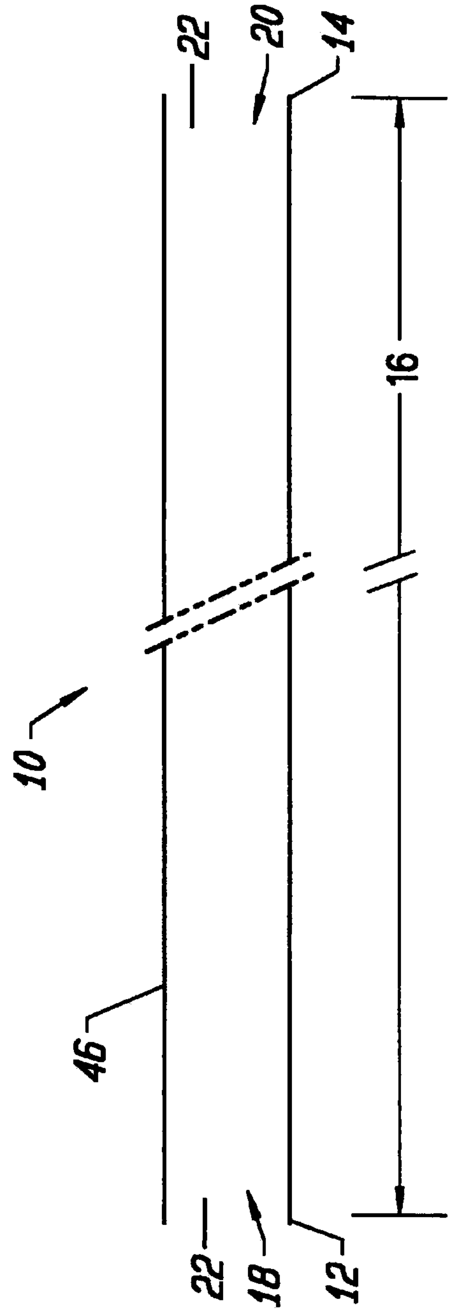


FIG. 1C

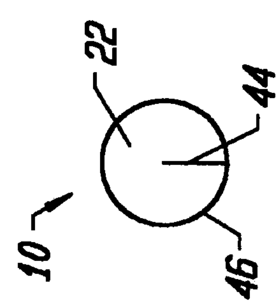


FIG. 1B

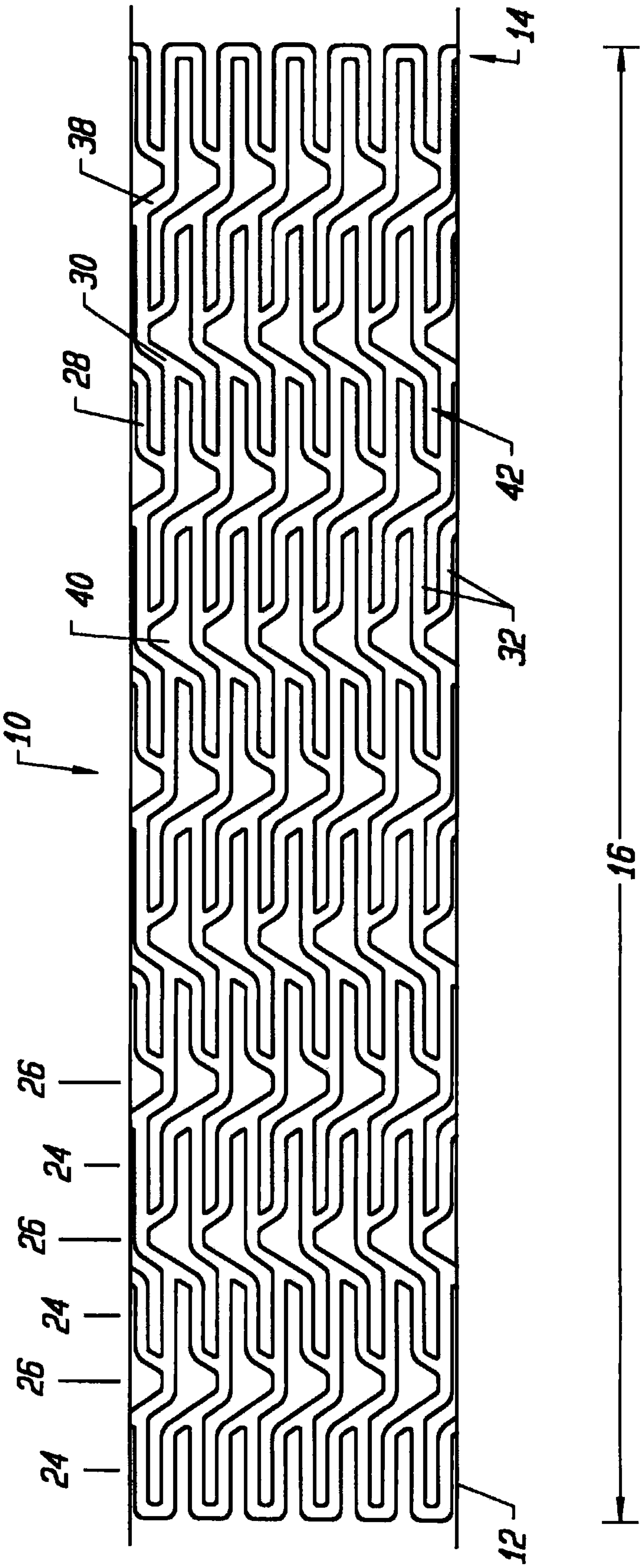


FIG. 2A

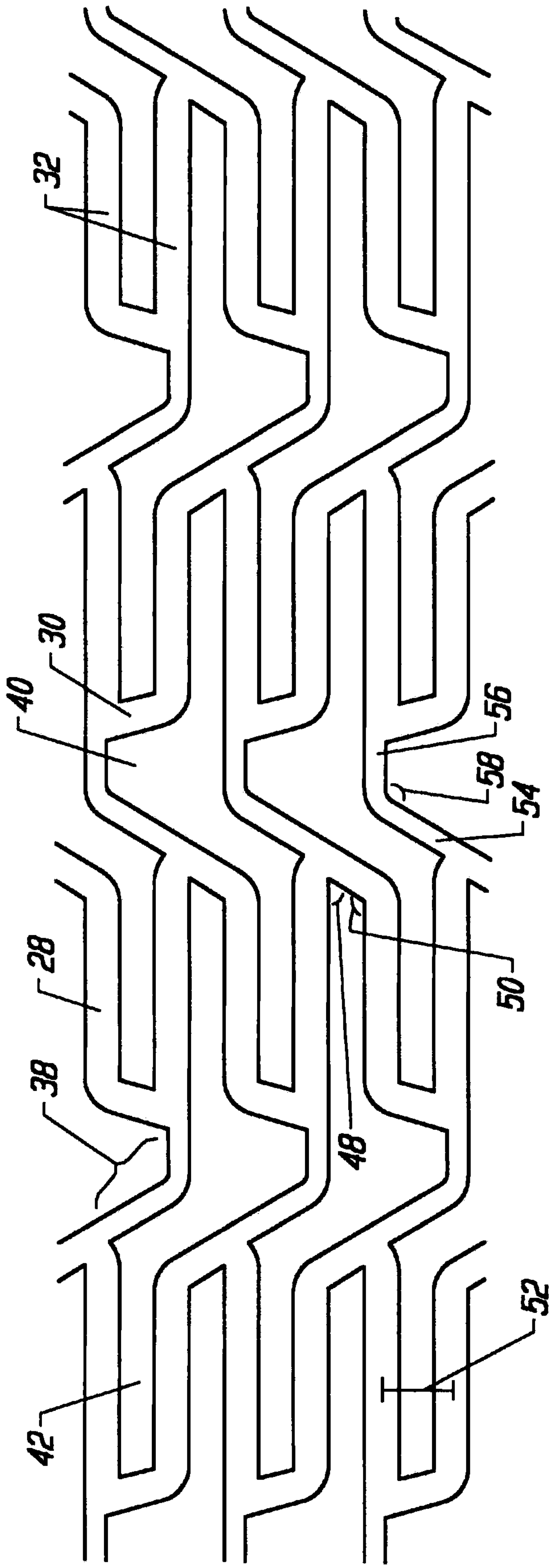


FIG. 2B

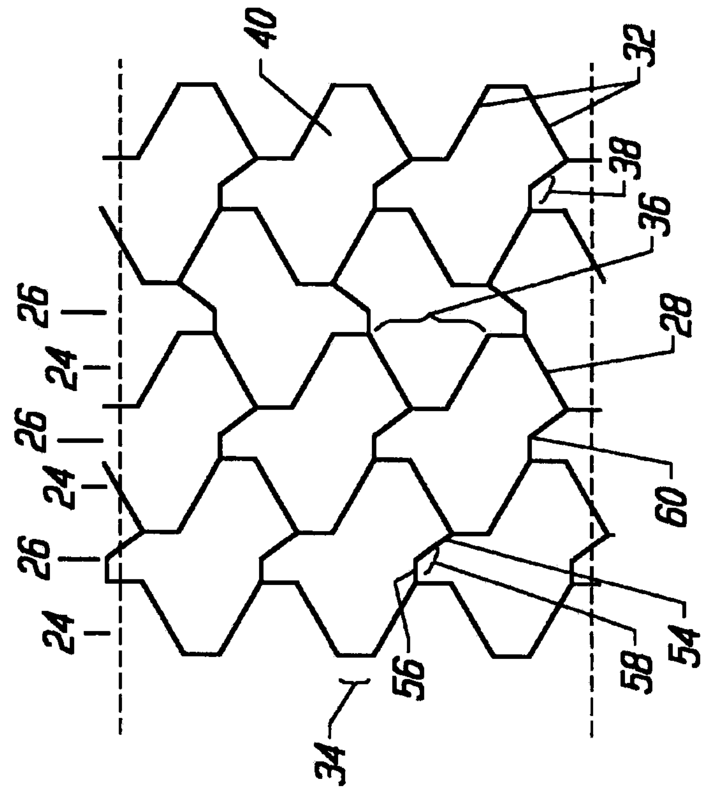

40
32
38
36
26
24
26
24
26
24
28
60
54
58
56
34

FIG. 3B

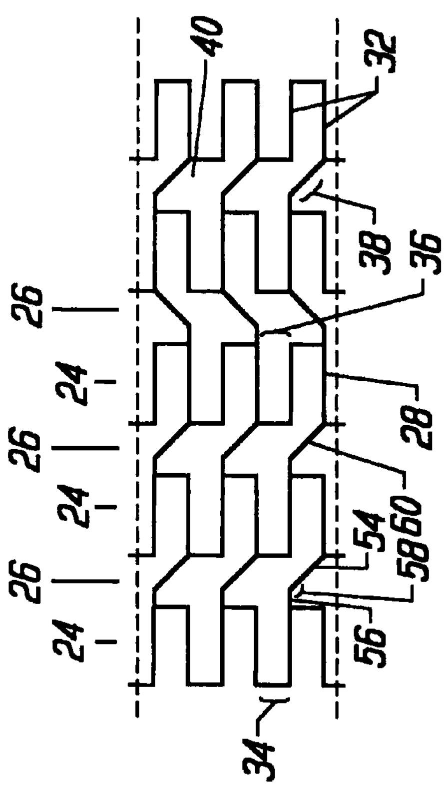

40
32
38
36
26
24
26
24
26
24
28
54
58
60
56
34

FIG. 3A

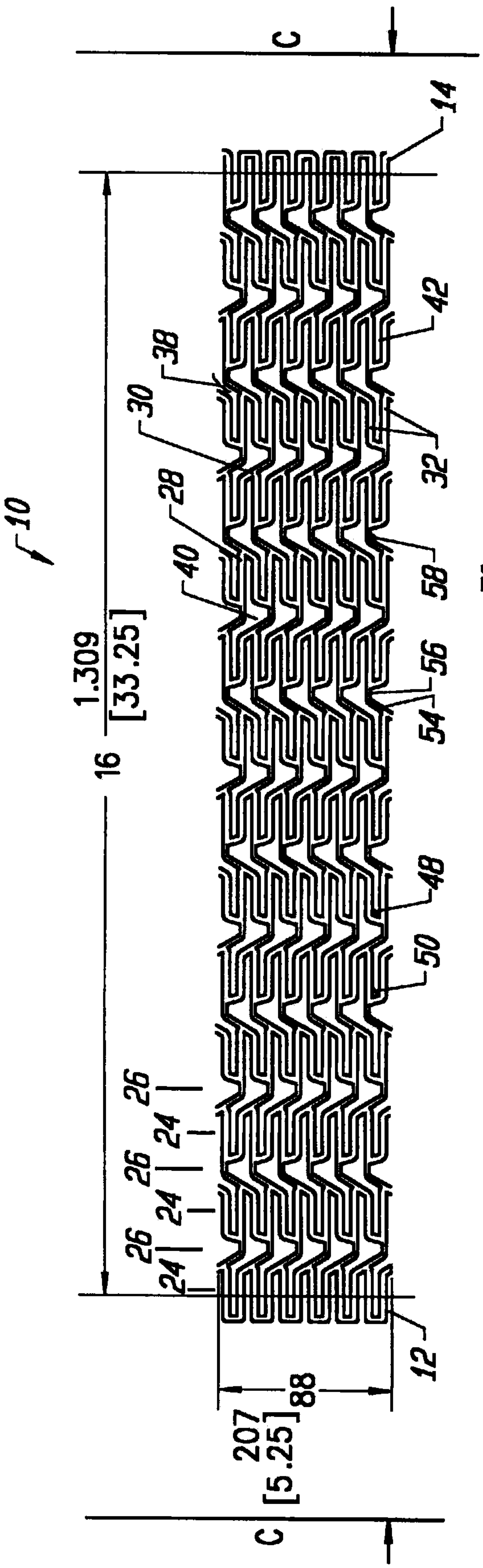

C
14
10
38
30
42
32
28
40
58
56
54
48
50
1.309
[33.25]
16
26
24
12
207
[5.25]
88
C

FIG. 4A

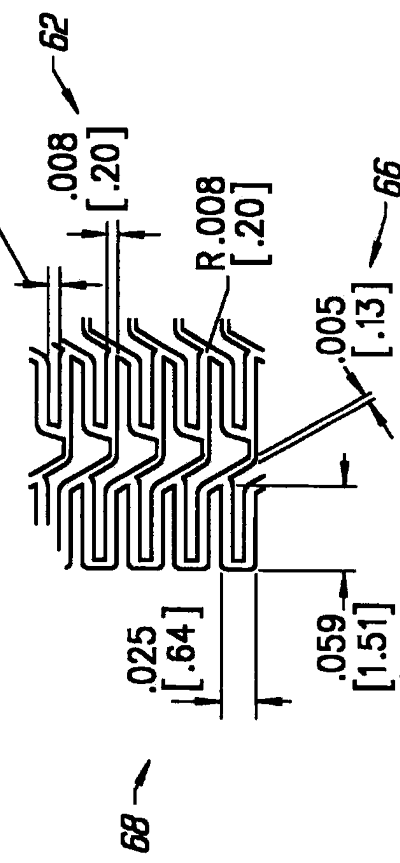
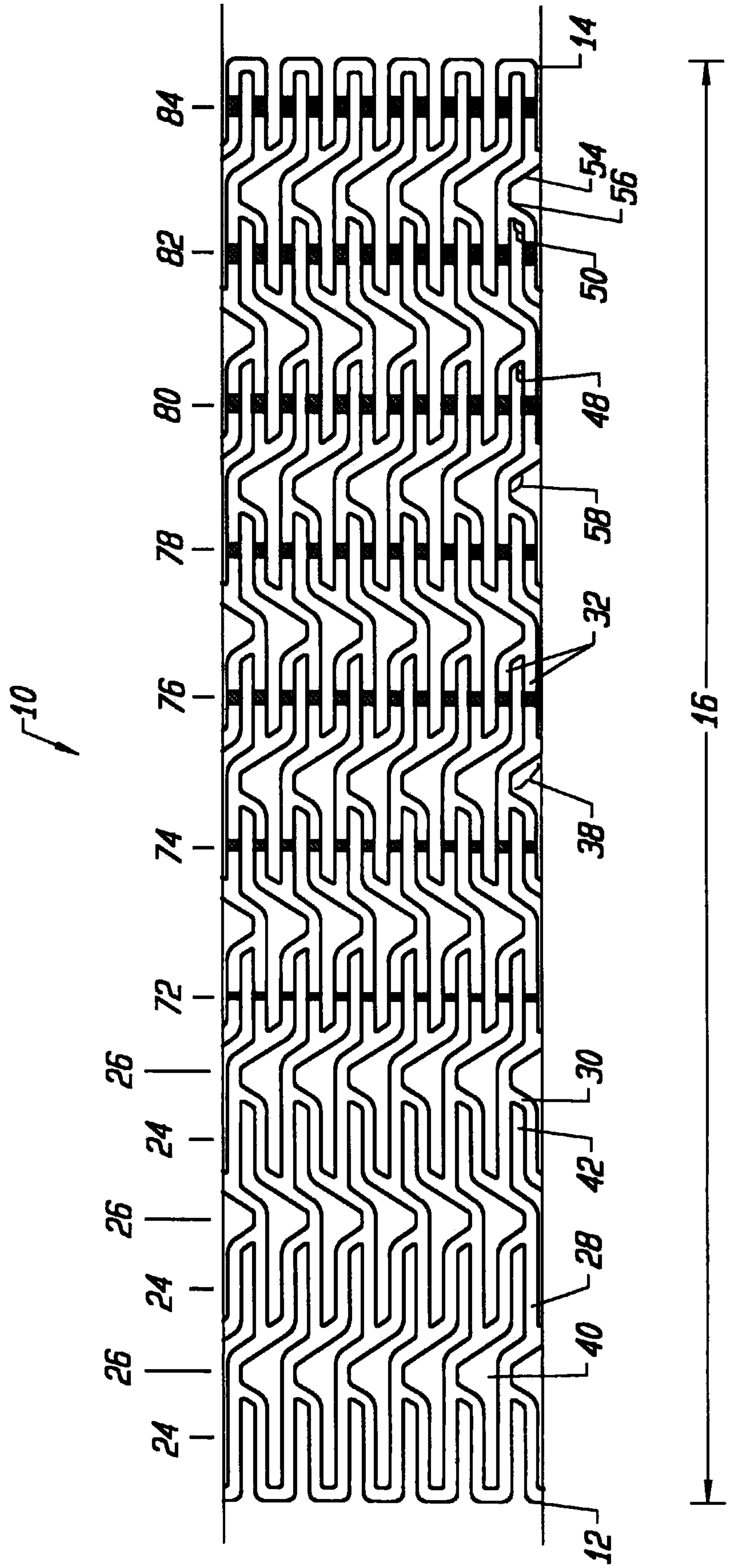

62
70
.008
[.20]
R.008
[.20]
66
.005
[.13]
.025
[.64]
.059
[1.51]
64
68

FIG. 4B



10
84
82
80
78
76
74
72
26
24
26
24
26
24
14
54
56
50
48
58
32
38
30
42
28
40
12
16

FIG. 5

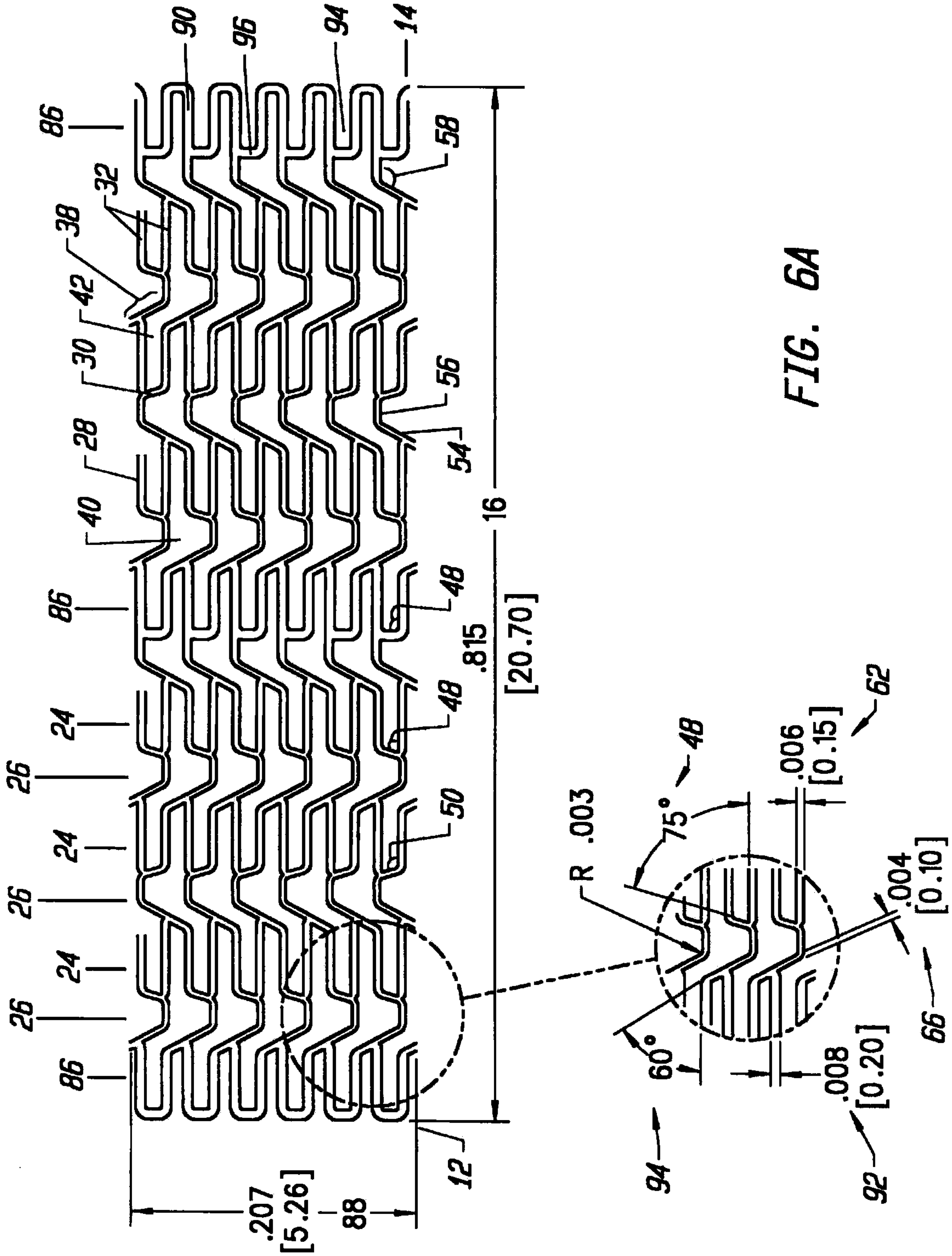

90
96
94
14
86
58
32
38
42
30
28
40
56
54
16
86
48
.815
[20.70]
48
24
26
24
26
24
26
86
50
12
.207
[5.26]
88
R .003
75°
48
.006
[0.15]
62
.004
[0.10]
60°
.008
[0.20]
94
92
66

FIG. 6A

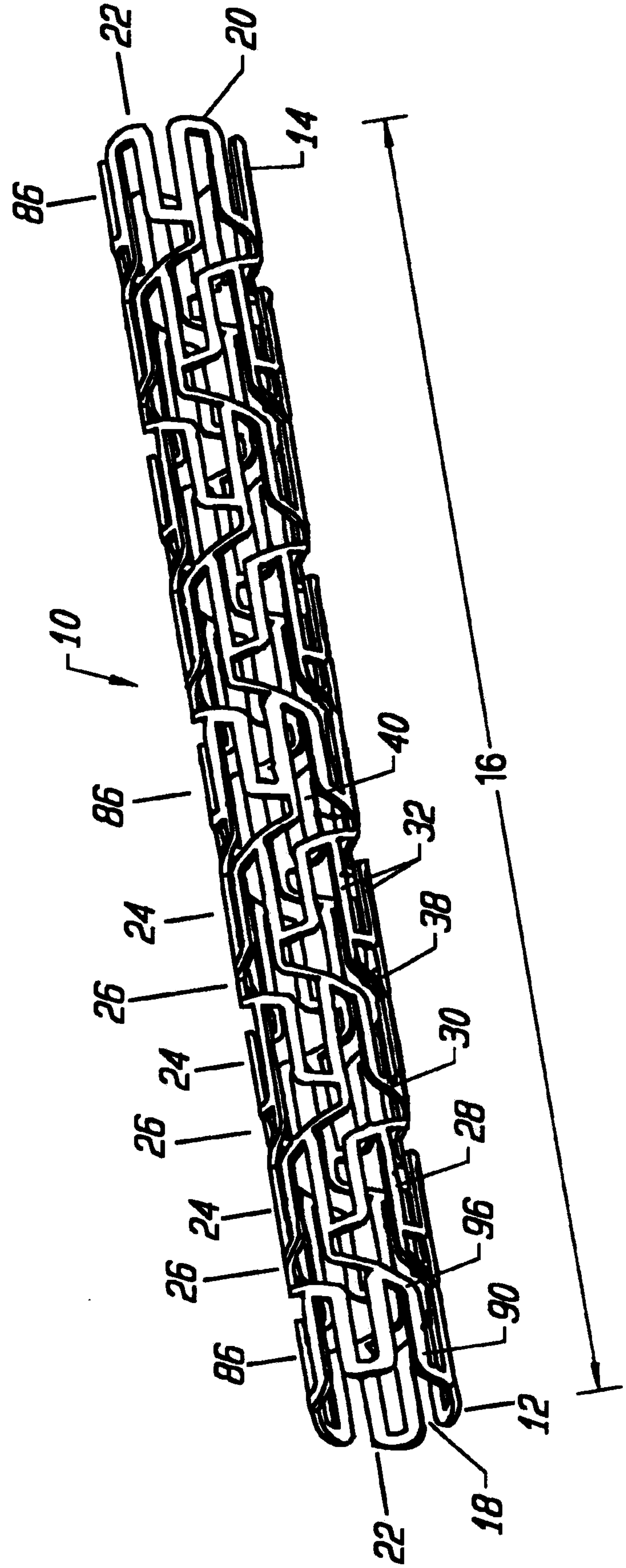


FIG. 6B

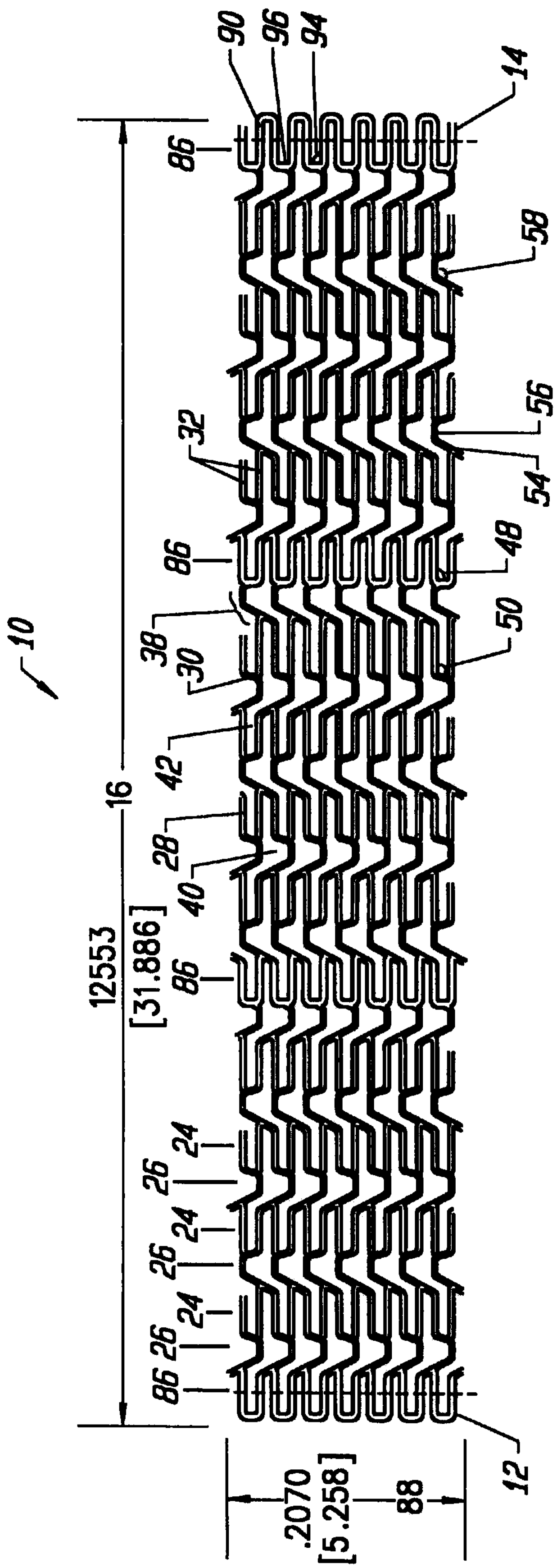

10
90
96
94
14
86
58
56
54
32
48
38
30
50
42
16
28
40
12553
[31.886]
24
26
.2070
[5.258]
88
12

FIG. 7A

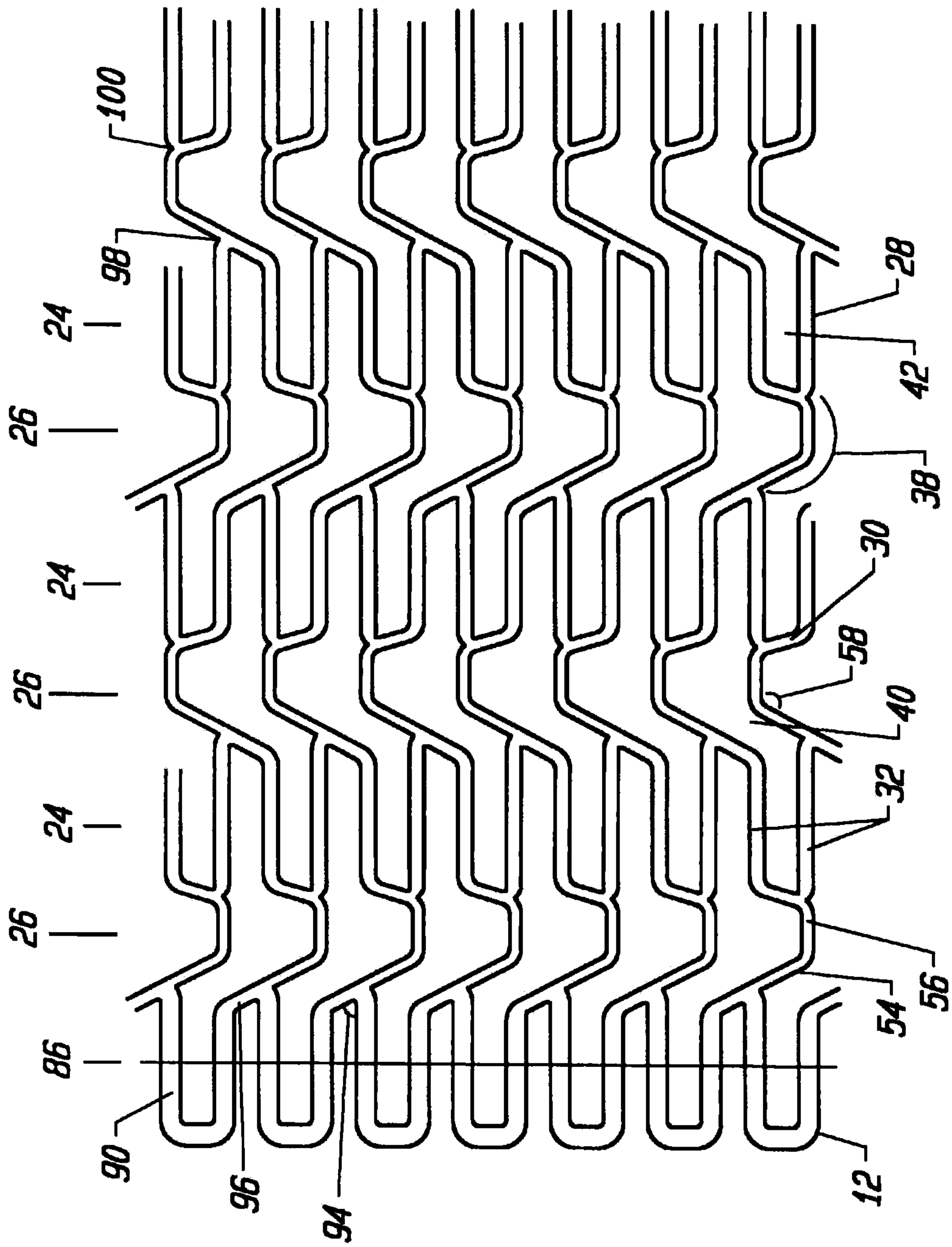


FIG. 7B

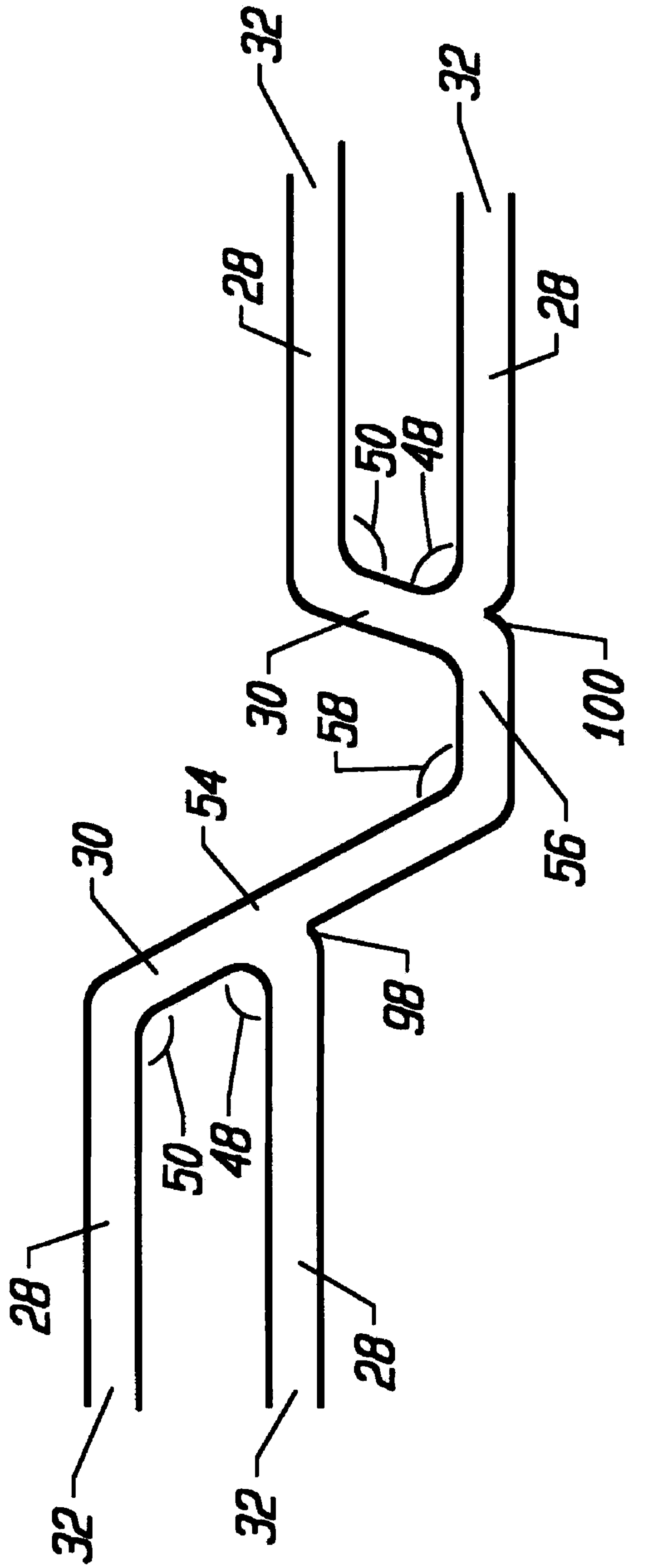
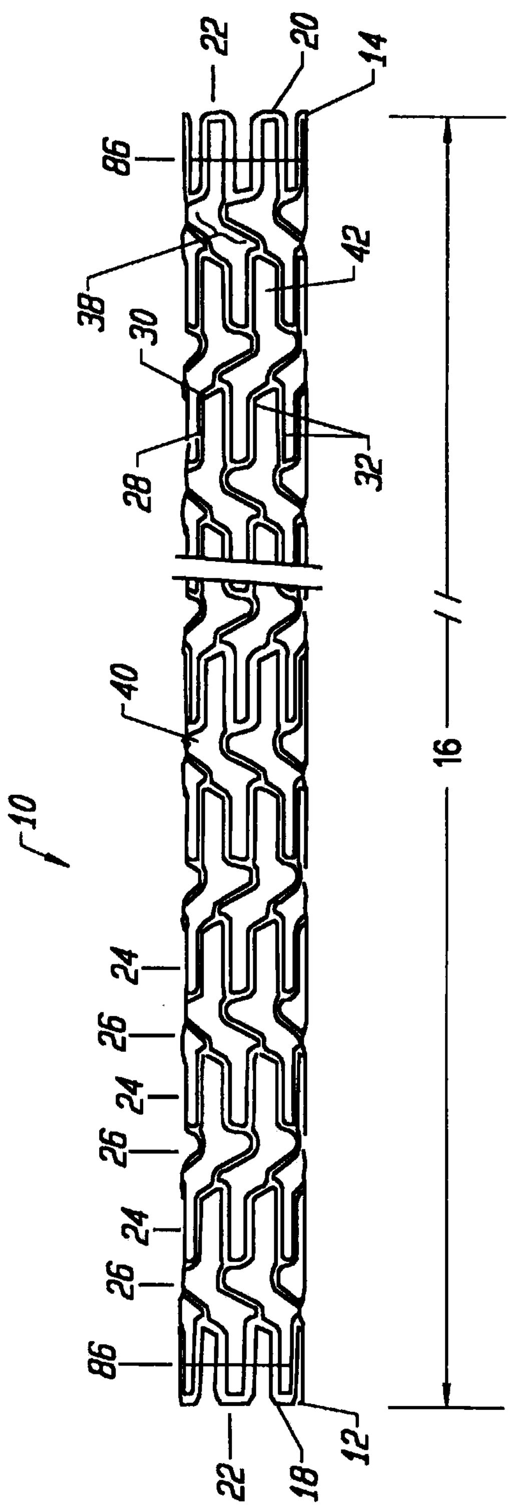
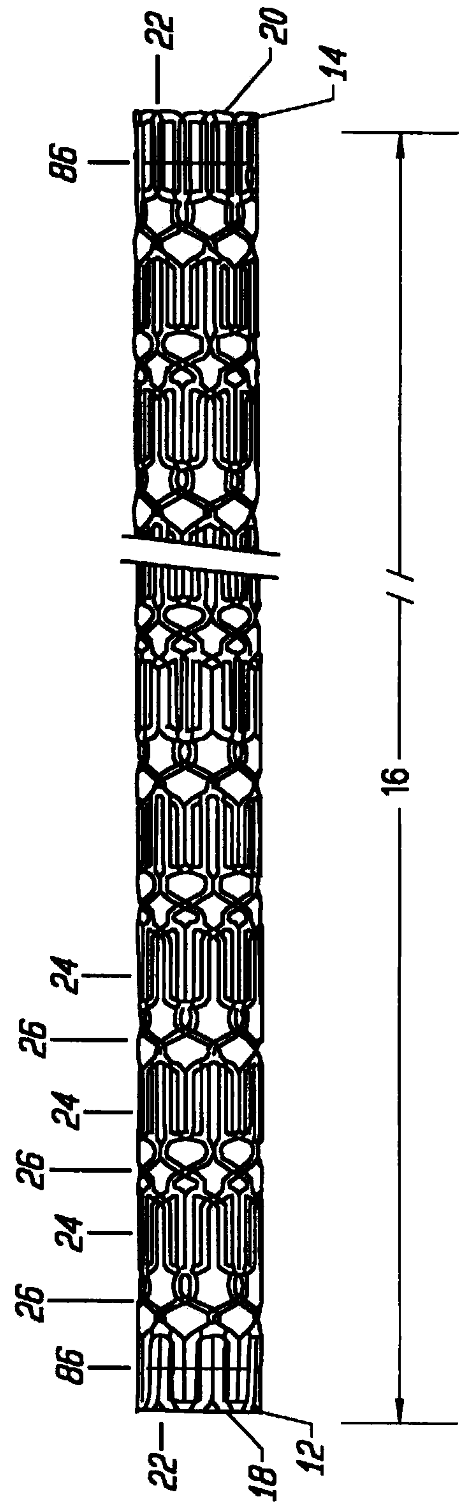


FIG. 7C



22
20
14
86
42
38
30
32
28
40
16
10
24
26
24
26
24
26
86
22
18
12

FIG. 8A



22
20
14
86
16
24
26
24
26
24
26
86
22
18
12

FIG. 8B

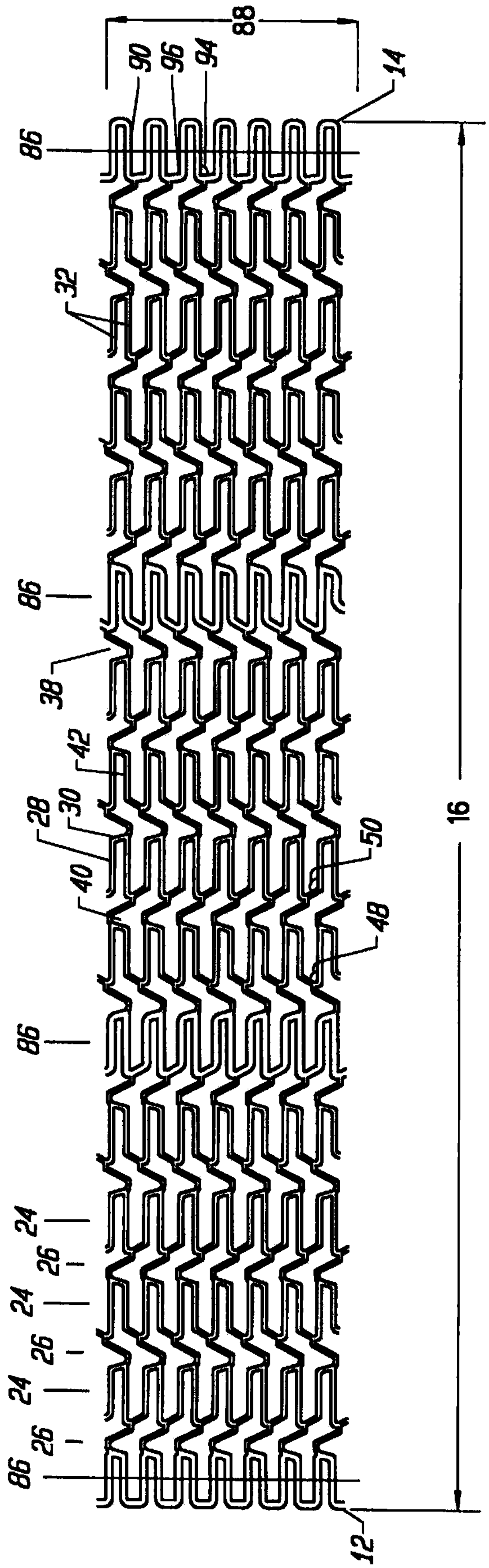

88
90
96
94
14
86
32
86
38
42
30
28
40
50
48
86
16
24
26
24
26
24
26
86
12

FIG. 8C

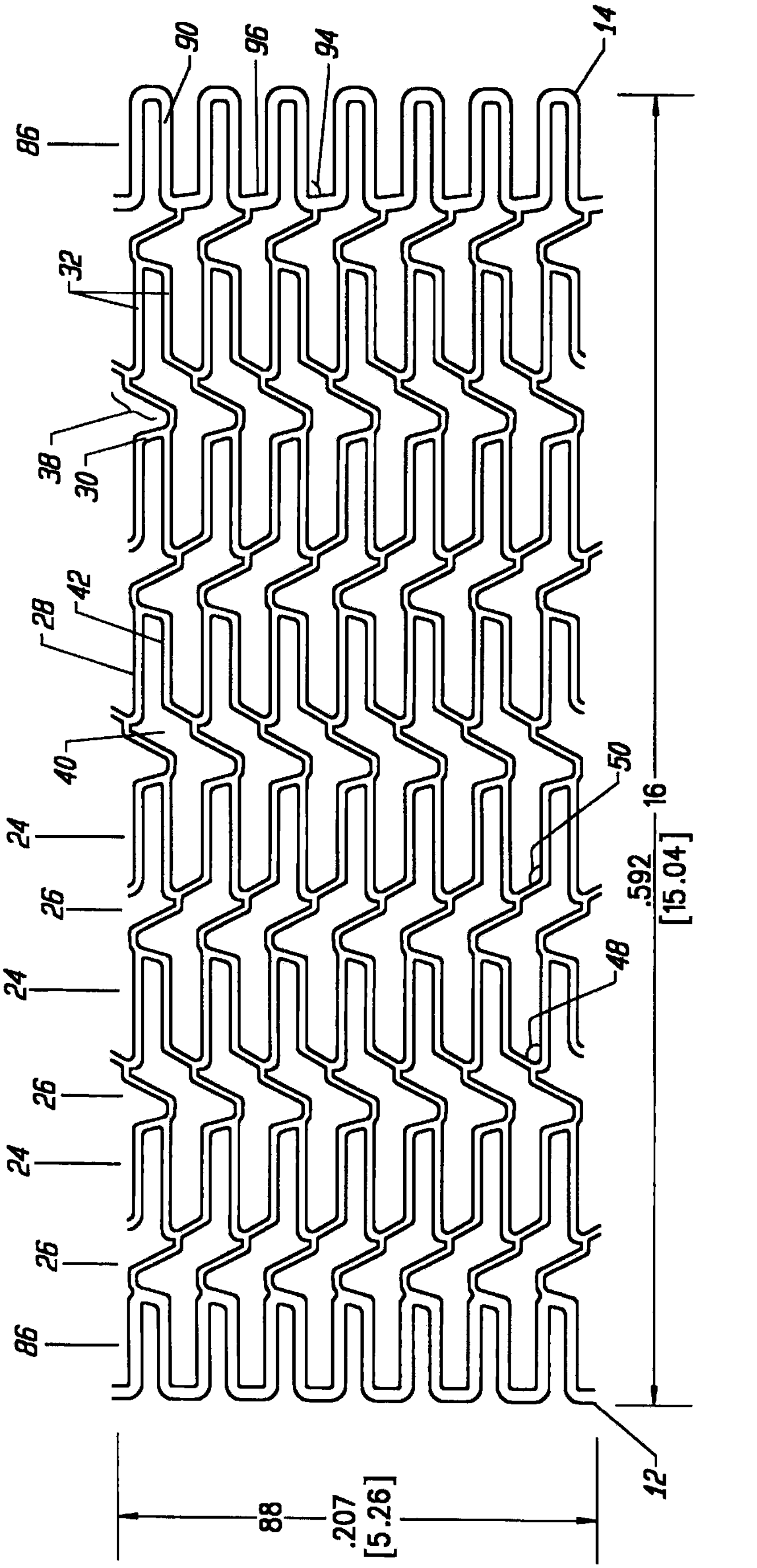

90
96
94
14
86
32
38
30
28
42
40
24
26
24
26
24
26
86
50
16
.592
[15.04]
48
12
88
.207
[5.26]

FIG. 8D

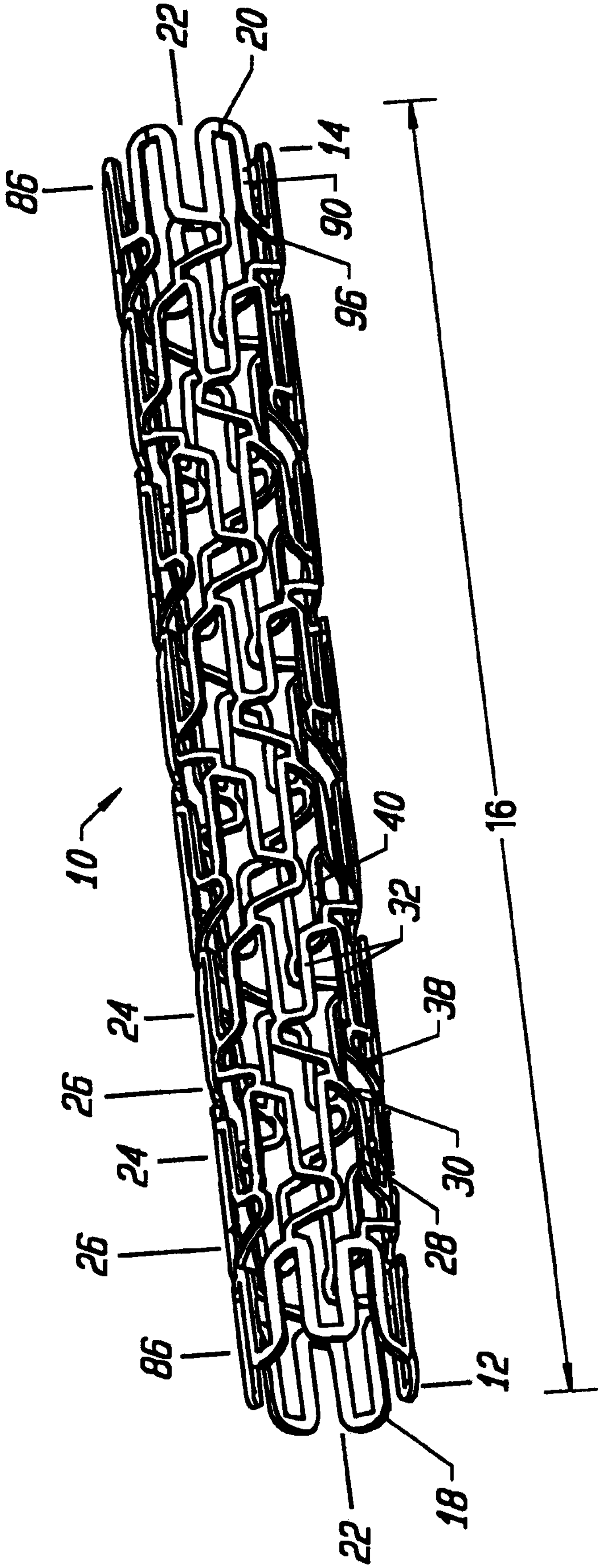


FIG. 8E

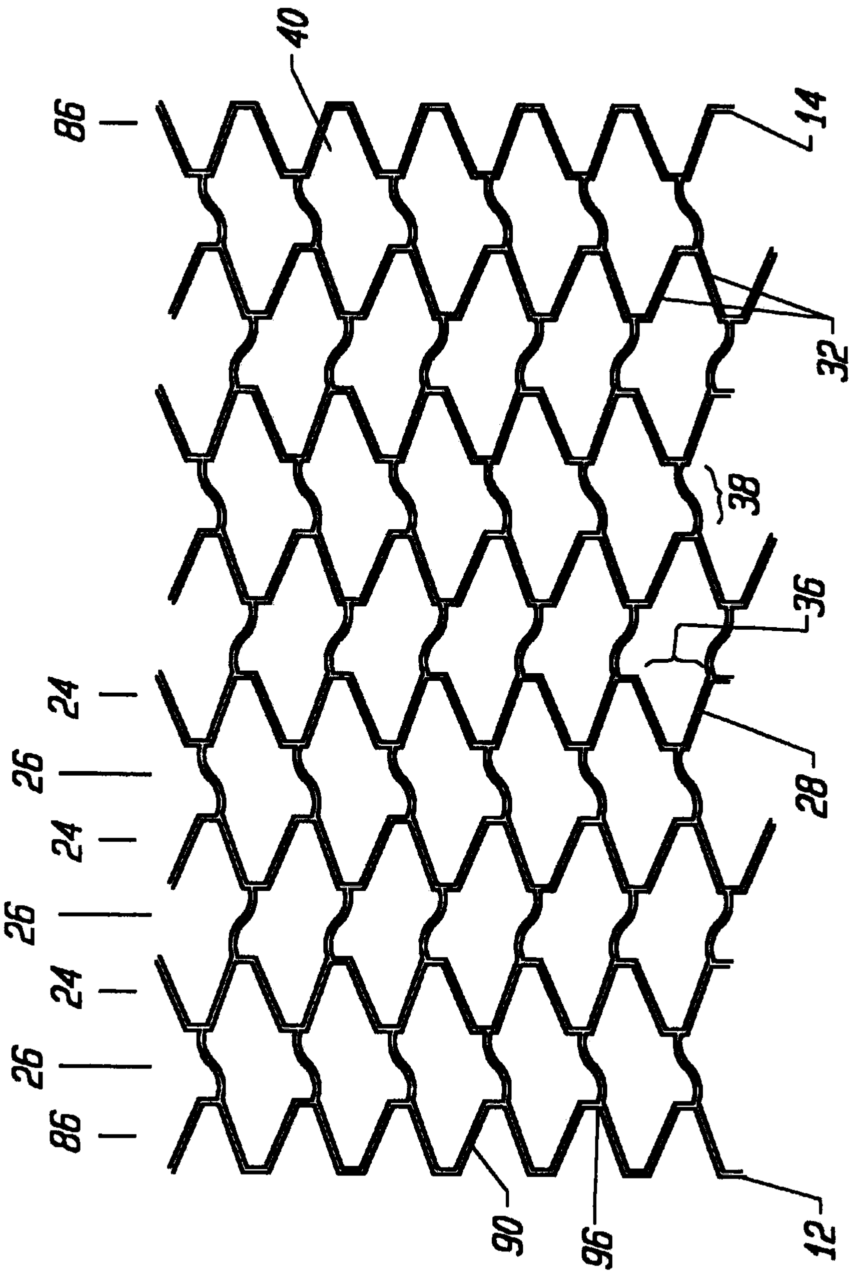


FIG. 8F

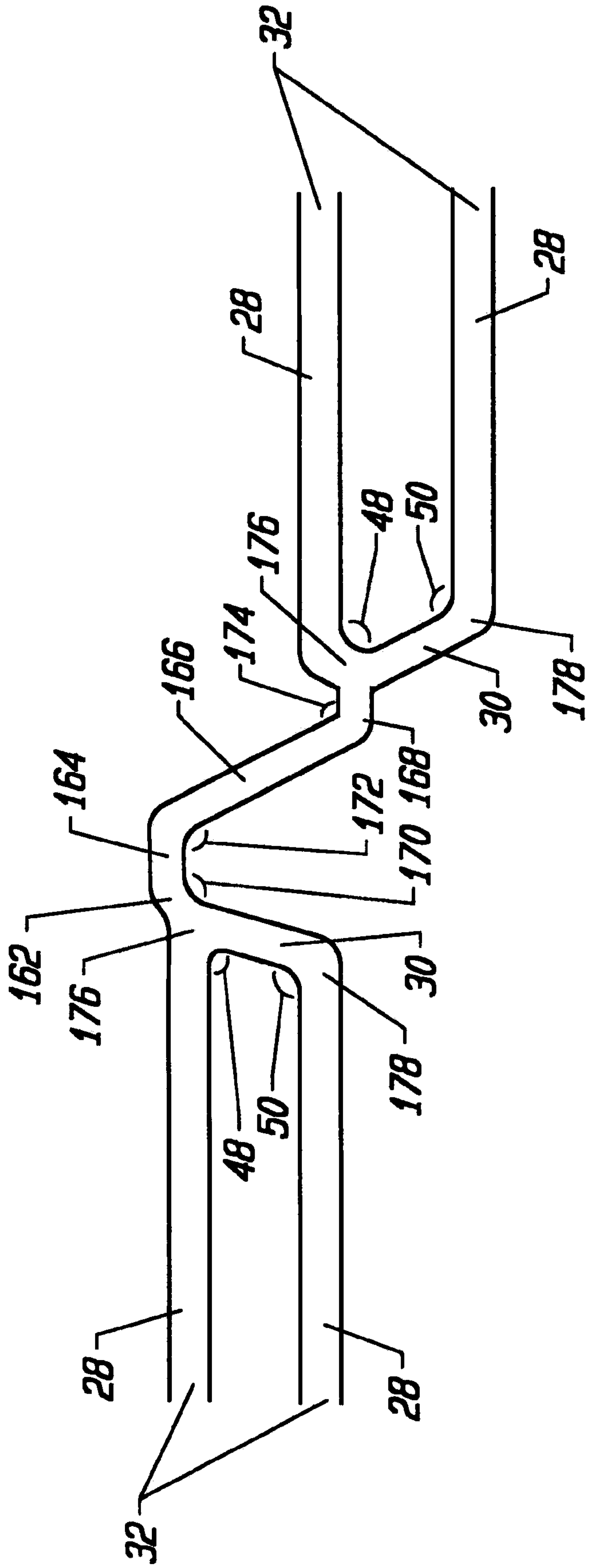
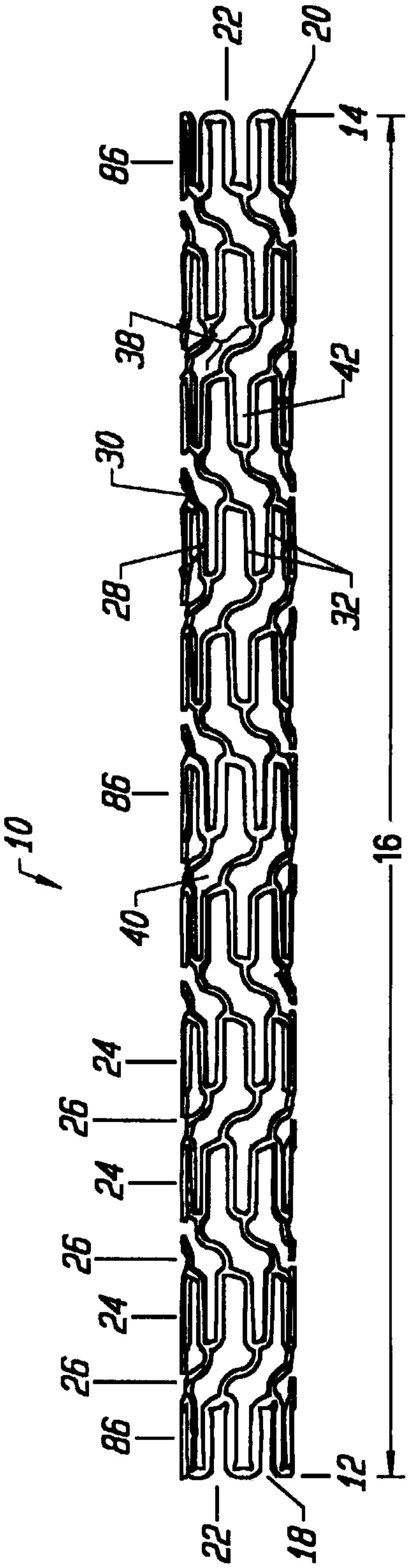
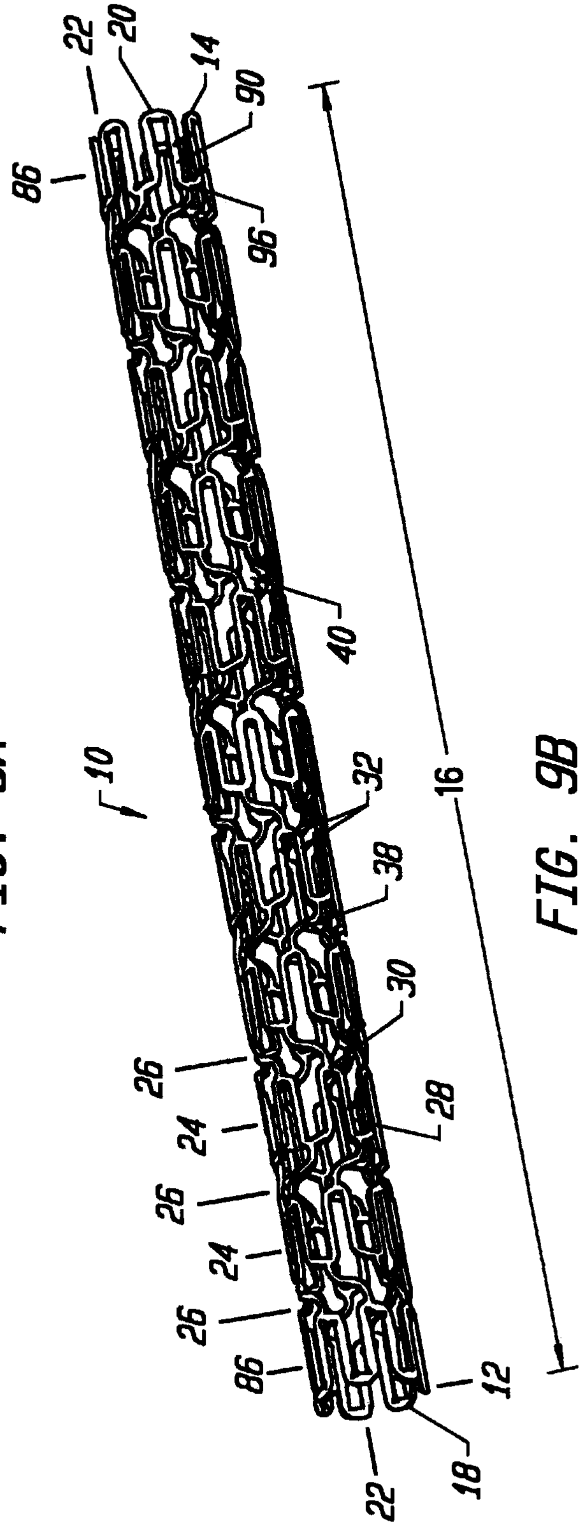

32
28
28
48
50
176
174
166
164
172
168
170
162
176
30
178
30
178
48
50
28
28
32

FIG. 8G



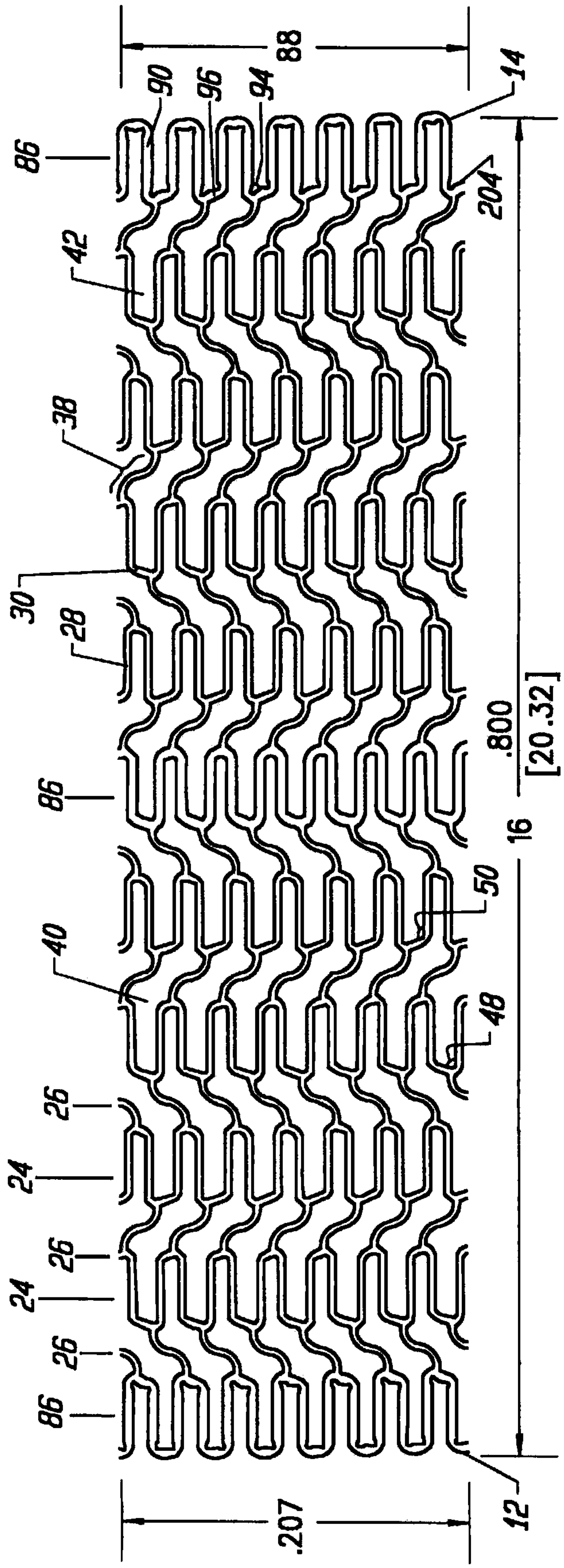
10
12
14
16
18
20
22
24
26
28
30
32
38
40
42
86

FIG. 9A



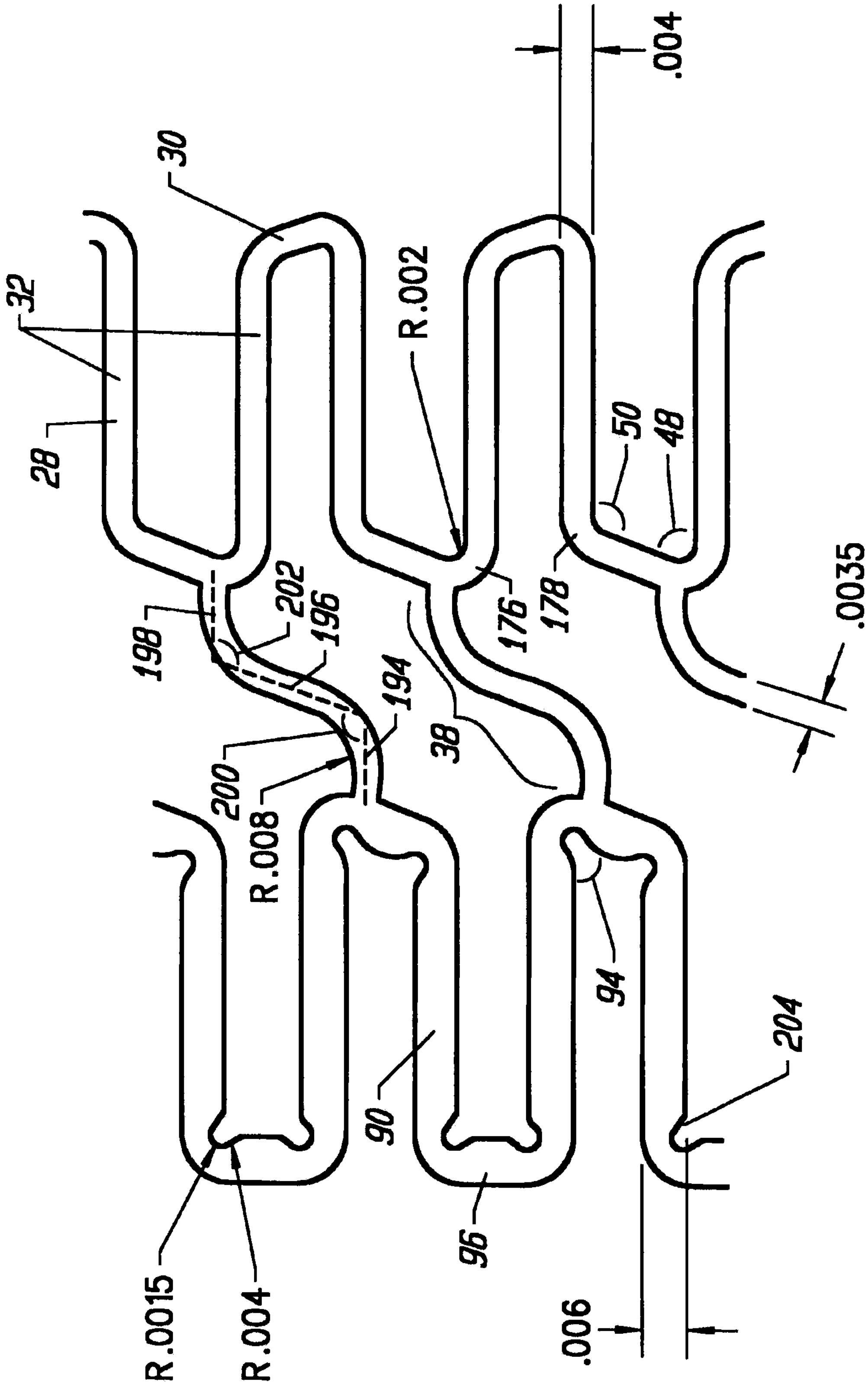
10
12
14
16
18
20
22
24
26
28
30
32
38
40
86
90
96

FIG. 9B



88
90
96
94
14
86
204
42
38
30
28
.800
[20.32]
86
16
50
40
48
26
24
26
24
26
86
.207
12

FIG. 9C



30
32
28
R.002
.004
50
48
198
202
196
194
176
178
.0035
38
200
R.008
94
90
204
96
R.0015
R.004
.006

FIG. 9D

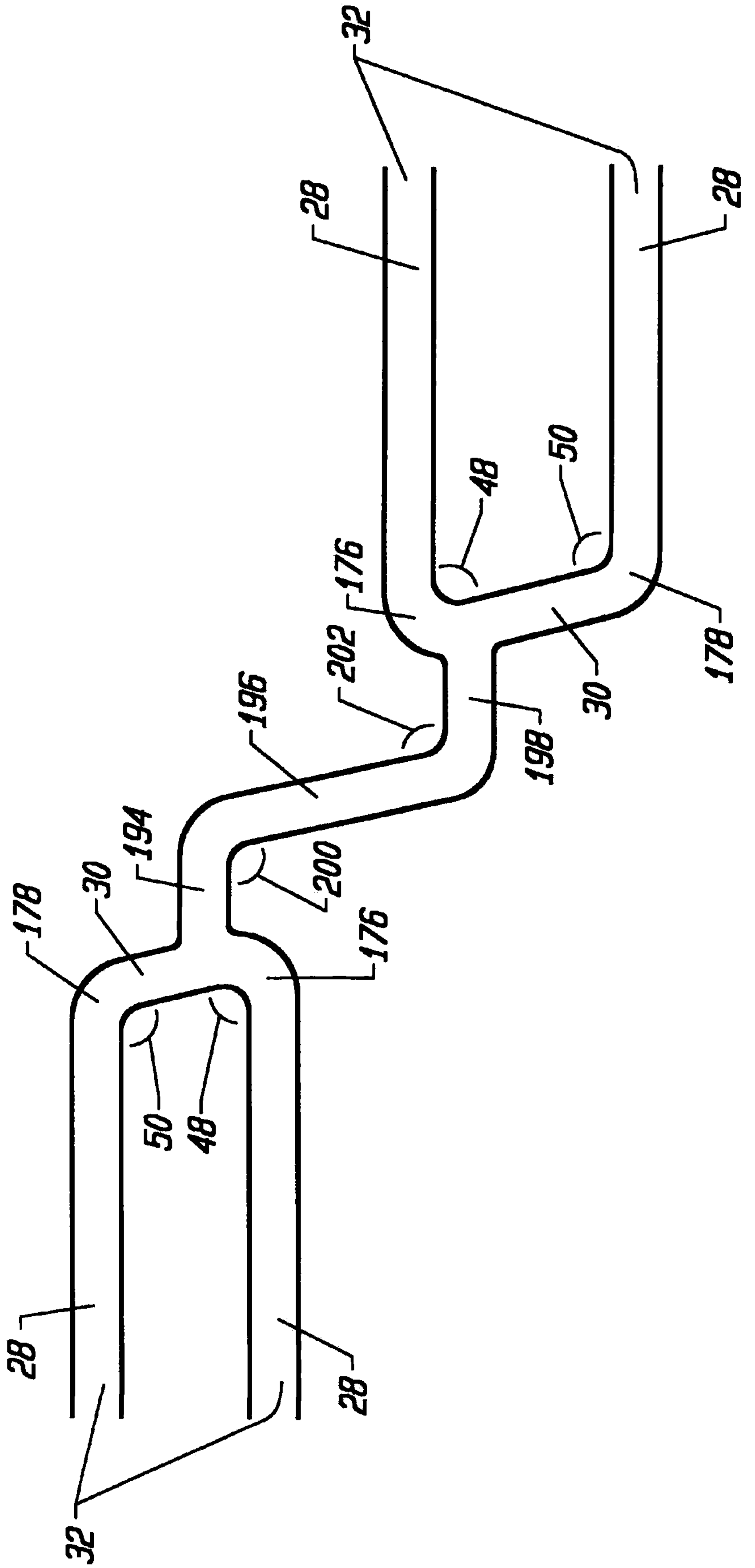

32
28
28
48
50
176
202
196
30
178
198
194
200
178
30
176
50
48
28
28
32

FIG. 9E

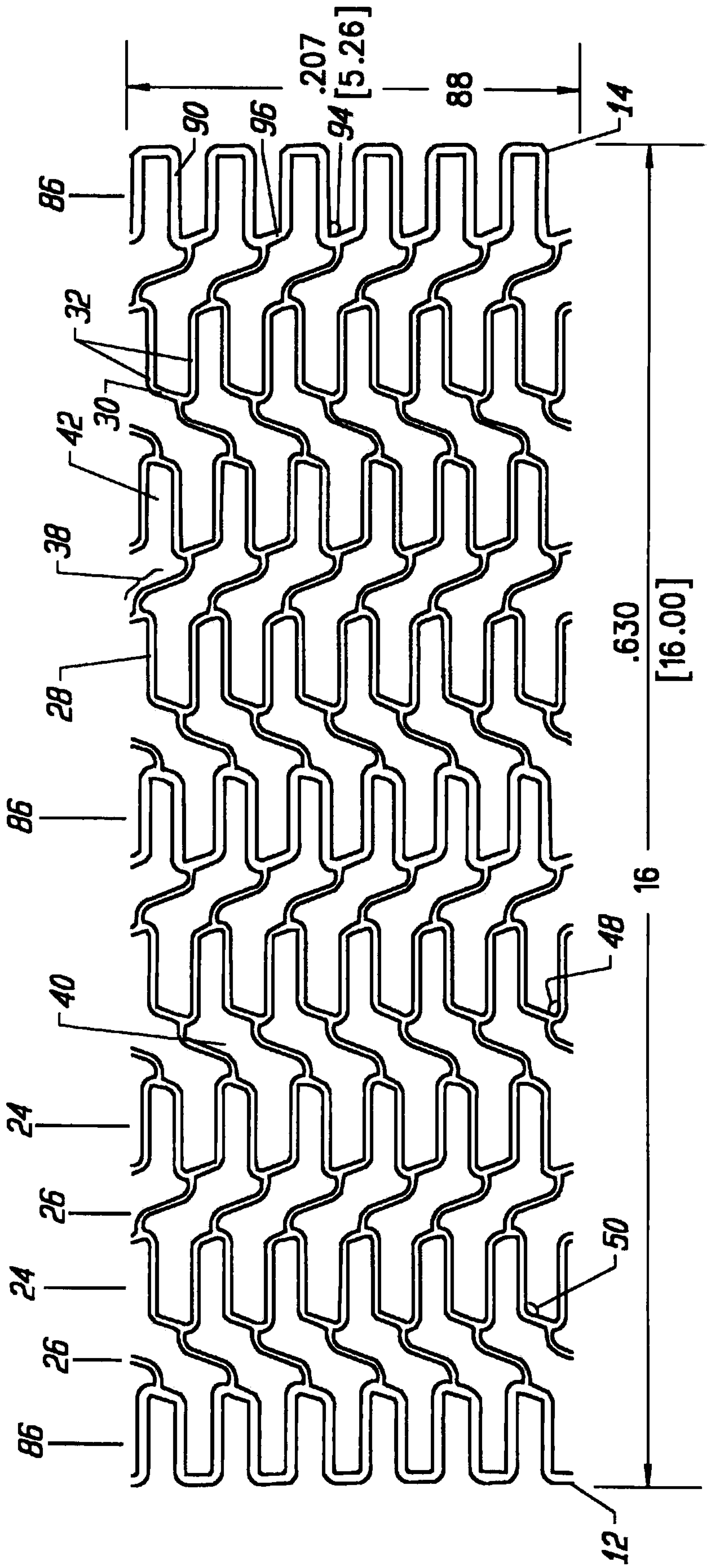

.207
[5.26]
88
90
96
94
14
86
32
30
42
38
28
86
40
24
26
24
26
86
48
50
.630
[16.00]
16
12

FIG. 9F

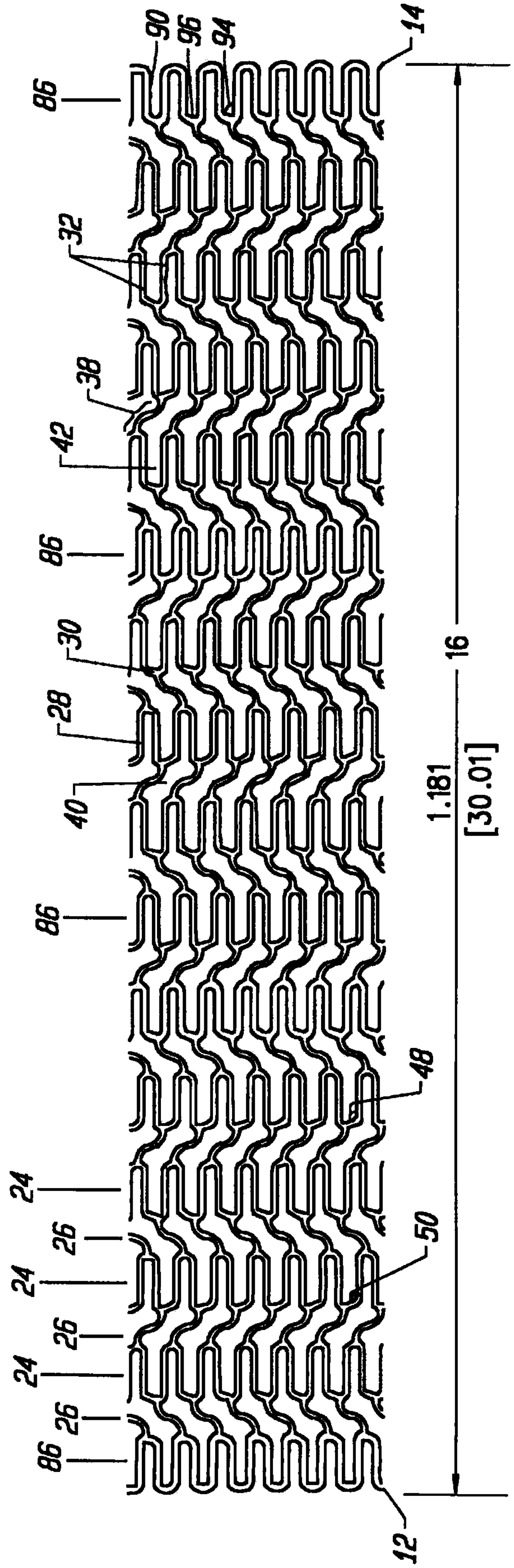

90
96
94
14
86
32
38
42
86
30
28
40
86
48
24
26
24
26
24
26
86
50
12
16
1.181
[30.01]

FIG. 9G

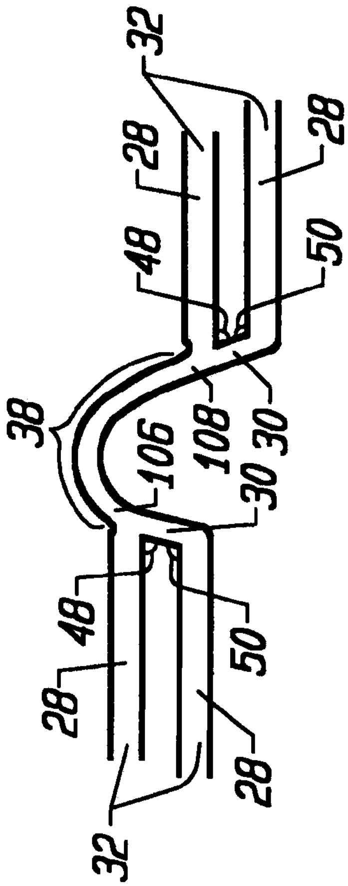


FIG. 10A

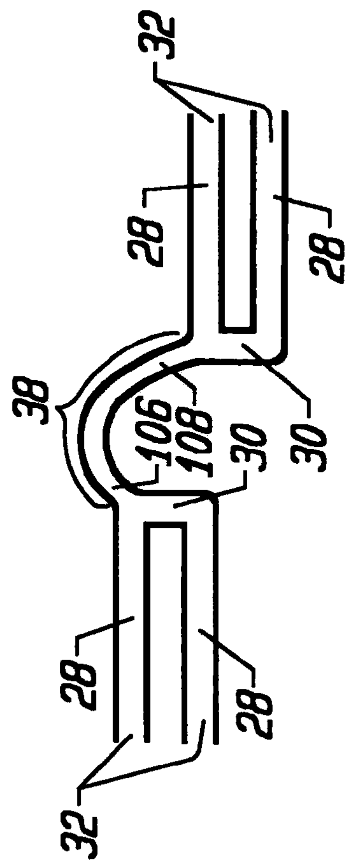


FIG. 10B

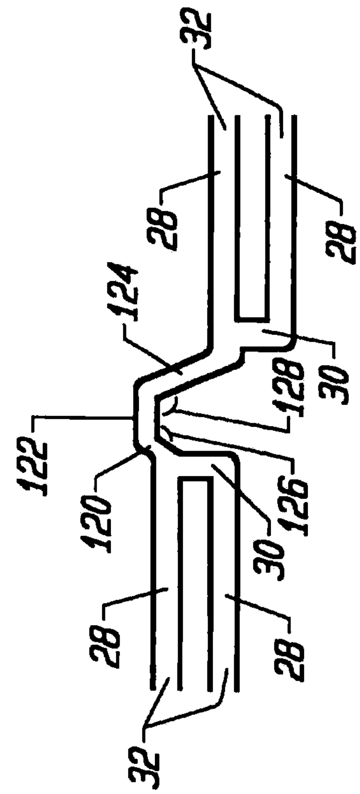


FIG. 10D

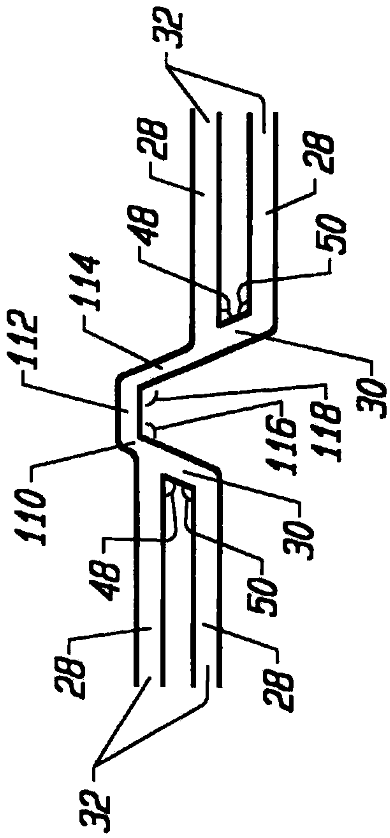


FIG. 10C

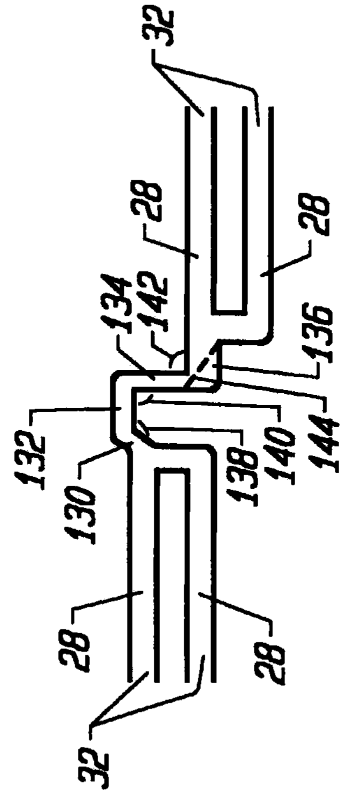


FIG. 10E

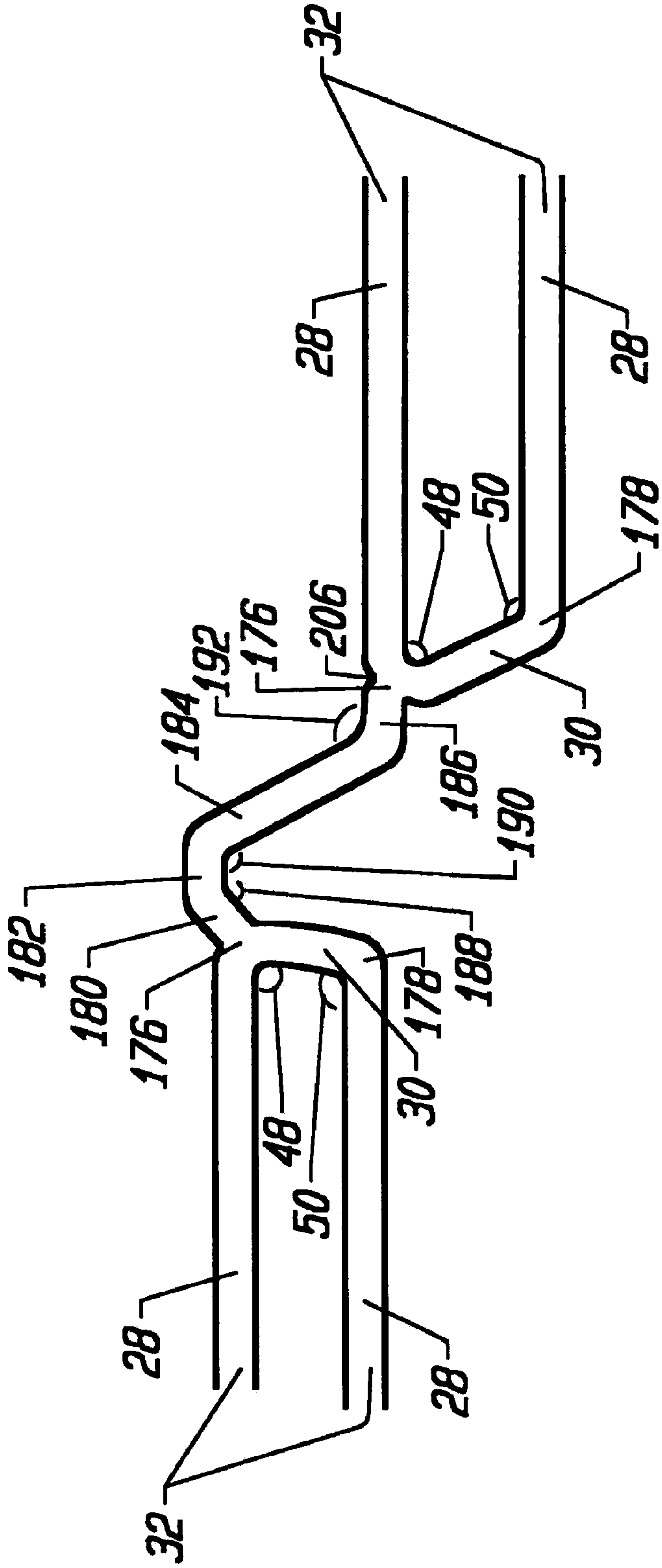

32
28
28
48
50
178
206
176
192
184
186
30
190
182
180
176
178
188
30
48
50
28
28
32

FIG. 10F

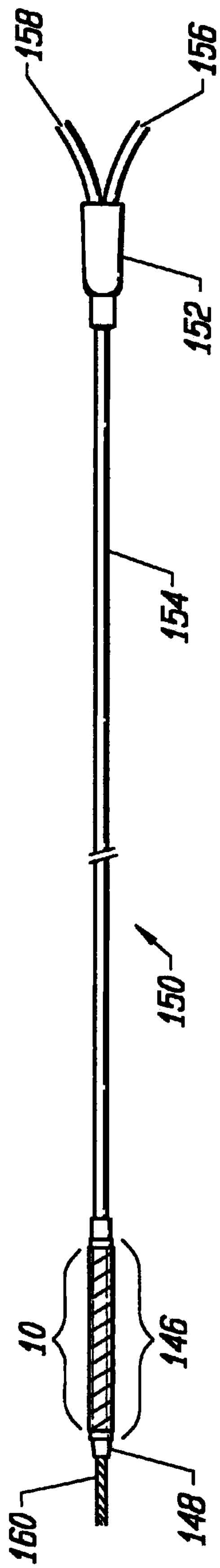


FIG. 11

INTRAVASCULAR STENT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of Provisional Patent Application No. 60/017,484 filed Apr. 26, 1996, the disclosure of which is incorporated by reference. This application is a continuation in part of U.S. patent application Ser. No. 08/824,142, filed Mar. 25, 1997, entitled "Intravascular Stent", and a continuation in part of U.S. Pat. application Ser. No. 08/824,866, filed Mar. 25, 1997, entitled "Intravascular Stent", and a continuation in part of U.S. patent application Ser. No. 08/824,865, filed Mar. 25, 1997, entitled "Intravascular Stent" and is related to U.S. patent application Ser. No. 08/845,734, filed Apr. 25, 1997, entitled "Intravascular Stent" each having same named inventor G. David Jang and being incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to intravascular stents, and more particularly to an intravascular stent which provides easy introduction through tortuous sections of vessels.

2. Description of the Related Art

Angioplasty, either coronary or general vascular, has advanced to become the most effective means for revascularization of stenosed vessels. In the early 1980's, angioplasty first became available for clinical practice in the coronary artery, and has since proven an effective alternative to conventional bypass graft surgery. Balloon catheter dependent angioplasty has consistently proven to be the most reliable and practical interventional procedure. Other ancillary technologies such as laser based treatment, or directional or rotational arthrectomy, have proven to be either of limited effectiveness or dependent on balloon angioplasty for completion of the intended procedure. Restenosis following balloon-based angioplasty is the most serious drawback and is especially prevalent in the coronary artery system.

Many regimens have been designed to combat restenosis, with limited success, including laser based treatment and directional or rotational arthrectomy. Intravascular stenting, however, noticeably reduces the restenosis rate following angioplasty procedures. The procedure for intravascular stent placement typically involves pre-dilation of the target vessel using balloon angioplasty, followed by deployment of the stent, and expansion of the stent such that the dilated vessel walls are supported from the inside.

The intravascular stent functions as scaffolding for the lumen of a vessel. The scaffolding of the vessel walls by the stent serve to: (a) prevent elastic recoil of the dilated vessel wall, (b) eliminate residual stenosis of the vessel; a common occurrence in balloon angioplasty procedures, (c) maintain the diameter of the stented vessel segment slightly larger than the native unobstructed vessel segments proximal and distal the stented segment and (d) as indicated by the latest clinical data, lower the restenosis rate. Following an angioplasty procedure, the restenosis rate of stented vessels has proven significantly lower than for unstented or otherwise treated vessels; treatments include drug therapy and other methods mentioned previously.

Another benefit of vessel stenting is the potential reduction of emergency bypass surgery arising from angioplasty procedures. Stenting has proven to be effective in some cases for treating impending closure of a vessel during

angioplasty. Stenting can also control and stabilize an unstable local intimal tear of a vessel caused by normal conduct during an angioplasty procedure. In some cases, an incomplete or less than optimal dilatation of a vessel lesion with balloon angioplasty can successfully be opened up with a stent implant.

Early in its development, the practice of stenting, especially in coronary arteries, had serious anticoagulation problems. However, anticoagulation techniques have since been developed and are becoming simpler and more effective. Better and easier to use regimens are continuously being introduced, including simple outpatient anticoagulation treatments, resulting in reduced hospital stays for stent patients.

An example of a conventional stent patent is U.S. Pat. No. 5,102,417 (hereafter the Palmaz Patent). The stent described in the Palmaz Patent consists of a series of elongated tubular members having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular members. The tubular members are connected by at least one flexible connector member.

The unexpanded tubular members of the Palmaz Patent are overly rigid so that practical application is limited to short lengths. Even with implementation of the multilink design with flexible connector members connecting a series of tubular members, longer stents can not navigate tortuous blood vessels. Furthermore, the rigidity of the unexpanded stent increases the risk of damaging vessels during insertion. Foreshortening of the stent during insertion complicates accurate placement of the stent and reduces the area that can be covered by the expanded stent. There is, further, no method of programming the stent diameter along its longitudinal axis to achieve a tapered expanded stent, and no method of reenforcement of stent ends or other regions is provided for.

Another example of a conventional stent patent is WO 96/03092, the Brun patent. The stent described in the Brun patent is formed of a tube having a patterned shape, which has first and second meander patterns. The even and odd first meander patterns are 180 degrees out of phase, with the odd patterns occurring between every two even patterns. The second meander patterns run perpendicular to the first meander patterns, along the axis of the tube.

Adjacent first meander patterns are connected by second meander patterns to form a generally uniform distributed pattern. The symmetrical arrangement with first and second meander patterns having sharp right angled bends allows for catching and snagging on the vessel wall during delivery. Furthermore, the large convolutions in the second meander pattern are not fully straightened out during expansion reducing rigidity and structural strength of the expanded stent. There is, further, no method of programming the stent diameter along its longitudinal axis to achieve a tapering stent design, and no method of reenforcement of stent ends or other regions is provided for.

These and other conventional stent designs suffer in varying degrees from a variety of drawbacks including: (a) inability to negotiate bends in vessels due to columnar rigidity of the unexpanded stent; (b) lack of structural strength, axio-laterally, of the unexpanded stent; (c) significant foreshortening of the stent during expansion; (d) limited stent length; (e) constant expanded stent diameter; (f) poor crimping characteristics; and (g) rough surface modulation of the unexpanded stent.

There is a need for a stent with sufficient longitudinal flexibility in the unexpanded state to allow for navigation

through tortuous vessels. There is a further need for a stent that is structurally strong in the unexpanded state such that risk of damage or distortion during delivery is minimal. A further need exists for a stent that maintains substantially the same longitudinal length during expansion to allow greater coverage at the target site and simplify proper placement of the stent. Yet a further need exists for a stent design with sufficient longitudinal flexibility that long stents of up to 100 mm can be safely delivered through tortuous vessels. There is a need for a stent that is configured to expand to variable diameters along its length, such that a taper can be achieved in the expanded stent to match the natural taper of the target vessel. A need exists for a stent which, (i) can be crimped tightly on the expansion balloon while maintaining a low profile and flexibility, (ii) has a smooth surface modulation when crimped over a delivery balloon, to prevent catching and snagging of the stent on the vessel wall during delivery or (iii) with reenforcement rings on the ends or middle or both to keep the ends of the stent securely positioned against the vessel walls of the target blood vessel.

SUMMARY OF THE INVENTION

Accordingly an object of the present invention is to provide a scaffold for an interior lumen of a vessel.

Another object of the invention is to provide a stent which prevents recoil of the vessel following angioplasty.

A further object of the invention is to provide a stent that maintains a larger vessel lumen compared to the results obtained only with balloon angioplasty.

Yet another object of the invention is to provide a stent that reduces foreshortening of a stent length when expanded.

Another object of the invention is to provide a stent with increased flexibility when delivered to a selected site in a vessel.

A further object of the invention is to provide a stent with a low profile when crimped over a delivery balloon of a stent assembly.

Yet a further object of the invention is to provide a stent with reduced tuliping of a stent frame.

Another object of the invention is to provide a chain mesh stent that reduces vessel "hang up" in a tortuous vessel or a vessel with curvature.

A further object of the invention is to provide a chain mesh stent that increases radial and axio-lateral strength of the expanded stent.

These and other objects of the invention are achieved in a stent in a non-expanded state. A first expansion strut pair includes a first expansion strut positioned adjacent to a second expansion strut and adjoining strut couples the first and second expansion struts at a distal end of the first expansion strut pair. A plurality of the first expansion strut pair form a first expansion column.

A second expansion strut pair includes a first expansion strut positioned adjacent to a second expansion strut and a joining strut of the second expansion strut pair couples the first and second expansion struts at a proximal end of the second expansion strut pair. A plurality of the second expansion strut pair form a second expansion column.

A first connecting strut includes a first connecting strut proximal section, a first connecting strut distal section and a first connecting strut intermediate section. The first connecting strut proximal section is coupled to the distal end of the first expansion strut pair in the first expansion column and the first connecting strut distal section being coupled to the proximal end of the second expansion strut pair of the second expansion column. A plurality of the first connecting struts forms a first connecting strut column that couples the first expansion column to the second expansion column. A length of the first connecting strut proximal section is equal to a length of the first connecting strut distal section, and a length of the first connecting strut intermediate section is greater than the length of the first connecting strut proximal and distal sections.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1A** is a side elevation view of the pre-expansion mode of an embodiment of the stent of the present invention;

FIG. **1B** is a cross sectional view of an embodiment of the stent of the present invention;

FIG. **1C** is a longitudinal cross sectional view of an embodiment of the stent of the present invention;

FIG. **2A** is a scale drawing of the strut pattern of an embodiment of the stent of the present invention;

FIG. **2B** is an expanded view of a section of the pattern of FIG. **2A**;

FIG. **3A** is a schematic illustration of a pre-expansion mode of an embodiment of the stent of the present invention;

FIG. **3B** is a schematic illustration of the post-expansion mode of an embodiment of the stent of the present invention;

FIG. **4A** is a scale drawing including dimensions of an embodiment of the stent of the present invention;

FIG. **4B** is an enlarged section of the scale drawing of FIG. **4A**;

FIG. **5** is a scale drawing of an embodiment of the stent of the present invention with a tapered diameter in its post-expansion mode;

FIG. **6A** is a scale drawing of an embodiment of the stent of the present invention with reenforcement expansion columns;

FIG. **6B** is a perspective view of the embodiment of FIG. **6A**;

FIG. **7A** is a scale drawing of an embodiment of the stent of the present invention including relief notches at strut joints to increase flexibility of the joints;

FIG. **7B** is an enlarged region of the embodiment of FIG. **7A**;

FIG. **7C** is an enlarged view of a single connecting strut joining two expansion strut pairs in accordance with the embodiment of FIG. **7A**;

FIG. **8A** is a side elevation view of an embodiment of the stent of the present invention;

FIG. **8B** is a side elevation view of an embodiment of the stent of the present invention, shown as if the stent struts and space there between were transparent;

FIG. **8C** is a scale drawing of an embodiment of the stent of the present invention;

FIG. **8D** is a variation of the embodiment of the stent of FIG. **8C**;

FIG. **8E** is a perspective view of the embodiment of FIG. **8D**;

FIG. **8F** is a drawing illustrating the post-expansion mode of the stent of the embodiment of FIG. **8D** of the present invention;

FIG. **8G** is an enlarged view of a single connecting strut joining two expansion strut pairs in accordance with an embodiment of the present invention;

FIG. **9A** is a side elevation view of an embodiment of the stent of the present invention;

FIG. 9B is a perspective view of the embodiment of FIG. 9A;

FIG. 9C is a scale drawing of the embodiment of FIG. 9A;

FIG. 9D is an enlarged region of the drawing of FIG. 9C;

FIG. 9E is a scale drawing of an embodiment of the stent of the present invention;

FIG. 9F is a scale drawing of an embodiment of the stent of the present invention;

FIG. 9G is an enlarged view of a single connecting strut joining two expansion strut pairs in accordance with an embodiment of the present invention;

FIG. 10A is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention;

FIG. 10B is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention;

FIG. 10C is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention;

FIG. 10D is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention;

FIG. 10E is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention;

FIG. 10F is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention; and

FIG. 11 is a delivery balloon catheter, illustrating a method of deliver of a stent in accord with the present invention.

DETAILED DESCRIPTION

A first embodiment of the present invention is shown in FIGS. 1A, 1B, 1C, 2A and 2B. Referring to FIG. 1A, an elongate hollow tubular stent **10** in an unexpanded state is shown. A proximal end **12** and a distal end **14** define a longitudinal length **16** of stent **10**. The longitudinal length **16** of the stent **10** can be as long as 100 mm or longer. A proximal opening **18** and a distal opening **20** connect to an inner lumen **22** of stent **10**. Stent **10** can be a single piece, without any seams or welding joints or may include multiple pieces.

Stent **10** is constructed of two to fifty or more expansion columns or rings **24** connected together by interspersed connecting strut columns **26**. The first column on the proximal end **12** and the last column on the distal end **14** of stent **10** are expansion columns **24**.

Expansion columns **24** are formed from a series of expansion struts **28**, and joining struts **30**. Expansion struts **28** are thin elongate members arranged so that they extend at least in part in the direction of the longitudinal axis of stent **10**. When an outward external force is applied to stent **10** from the inside by an expansion balloon or other means, expansion struts **28** are reoriented such that they extend in a more circumferential direction, i.e along the surface of cylindrical stent **10** and perpendicular to its longitudinal axis. Reorientation of expansion struts **28** causes stent **10** to have an expanded circumference and diameter. In FIG. 1A, expansion struts **28** of unexpanded stent **10** are seen to extend substantially parallel to the longitudinal axis of stent **10**.

Expansion struts **28** are joined together by joining struts **30** to form a plurality of expansion strut pairs **32**. Expansion

strut pairs have a closed end **34** and an open end **36**. Additional joining struts **30** join together expansion struts **28** of adjacent expansion strut pairs **32**, such that expansion struts **28** are joined alternately at their proximal and distal ends to adjacent expansion struts **28** to form expansion columns **24**. Each expansion column **24** contains a plurality, typically eight to twenty, twenty to sixty, or larger of expansion struts **28**. Expansion columns are preferably continuous unbroken ring structures extending around the circumference of the stent **10**; however, broken structures in which individual struts or pieces of struts are removed from an otherwise continuous expansion column **24** can also be used.

Connecting struts **38** connect adjacent expansion columns **24** forming a series of interspersed connecting strut columns **26** each extending around the circumference of stent **10**. Each connecting strut **38** joins a pair of expansion struts **28** in an expansion column **24** to an adjacent pair of expansion struts **28** in an adjacent expansion column **24**. For stent **10** of FIG. 1A, the ratio of expansion struts **28** in an expansion column **24** to connecting struts **38** in a connecting strut column **26** is two to one; however, this ratio in general can be x to 1 where x is greater or less than two. Furthermore, since the stent **10** of FIG. 1A begins with an expansion column **24** on the proximal end **12** and ends with an expansion column **24** on the distal end **14**, if there are n expansion columns **24** with m expansion struts **28** per column, there will be m-1 connecting strut columns **26**, and n(m-1)/2 connecting struts **38**.

The reduced number of connecting struts **38** in each connecting strut column **26**, as compared to expansion struts **28** in each expansion column **24**, allows stent **10** to be longitudinally flexibility. Longitudinal flexibility can be further increased by using a narrow width connecting strut, providing additional flexibility and suppleness to the stent as it is navigated around turns in a natural blood vessel.

At least a portion of the open spaces between struts in stent **10** form asymmetrical cell spaces **40**. A cell space or geometric cell is an empty region on the surface of stent **10**, completely surrounded by one or a combination of stent struts, including expansion struts **28**, connecting struts **38**, or joining struts **30**. Asymmetrical cell spaces **40** are cell spaces which have no geometrical symmetry i.e. no rotation, reflection, combination rotation and reflection or other symmetry. Asymmetrical cell spaces **40** have an asymmetrical geometric configuration.

Asymmetrical cell spaces **40** in FIG. 1A are surrounded by a first expansion strut pair **32** in a first expansion column **24**, a first connecting strut **38**, a second expansion strut pair **32** in an adjacent expansion column **24**, a first joining strut **30**, a second connecting strut **38**, and a second joining strut **30**. Furthermore, expansion strut pairs **32** of asymmetrical cell space **40** may be circumferentially offset i.e. have longitudinal axes that are not collinear and have their open ends **36** facing each other. The space between two expansion struts of an expansion strut pair **32** is known as a loop slot **42**.

FIG. 1B shows inner lumen **22**, radius **44** and stent wall **46** of stent **10**. Stent wall **46** consists of stent struts including expansion struts **28**, connecting struts **38** and joining struts **30**.

FIG. 1C shows, proximal end **12**, distal end **14**, longitudinal length **16**, inner lumen **22**, and stent wall **46** of stent **10**. Inner lumen **22** is surrounded by stent wall **46** which forms the cylindrical surface of stent **10**.

Referring now to FIGS. 2A and 2B, joining struts **30** of stent **10** are seen to extend at an angle to the expansion struts

28, forming a narrow angle 48 with one expansion strut 28 in an expansion strut pair 32 and a wide angle 50 with the other expansion strut 28 of an expansion strut pair 32. Narrow angle 48 is less than ninety degrees, while wide angle 50 is greater than ninety degrees. Joining struts 30 extend both longitudinally along the longitudinal axis of stent 10 and circumferentially, along the surface of the stent 1 0 perpendicular to its longitudinal axis.

Expansion strut spacing 52 between adjacent expansion struts 28 in a given expansion column 24 are uniform in stent 10 of FIGS. 2A and 2B; however, non-uniform spacings can also be used. Expansion strut spacings 52 can be varied, for example, spacings 52 between adjacent expansion struts 28 in an expansion column 24 can alternate between a narrow and a wide spacings. Additionally, spacings 52 in a single expansion column 24 can differ from other spacings 52 in other columns 24.

It is noted that varying expansion strut spacings 52 which form the loop slots 42 results in variable loop slot widths. Furthermore, the longitudinal axis of the loop slots 42 need not be collinear or even parallel with the longitudinal axis of loop slots 42 of an adjacent expansion column 24. FIGS. 2A and 2B show an arrangement of expansion struts 28 such that collinear, parallel adjacent loop slots 42 are formed, but non-collinear and non-parallel loop slots 42 can also be used.

Additionally the shape of loop slots 42 need not be the same among loop slots of a single or multiple expansion columns 24. The shape of loop slots 42 can be altered by changing the orientation or physical dimensions of the expansion struts 28 and/or joining struts 30 which connect expansion struts 28 of expansion strut pairs 32 defining the boundaries of loop slots 42.

Connecting struts 38 couple adjacent expansion columns 24, by connecting the distal end of an expansion strut pair in one expansion column 24 to the proximal end of an adjacent expansion strut pair 32 in a second expansion column 24. Connecting struts 38 of FIGS. 2A and 2B are formed from two linear sections, a first linear section 54 being joined at its distal end to a second linear section 56 at its proximal end to form a first slant angle 58.

The first linear section 54 of a connecting strut 38 is joined to expansion strut 28 at the point where joining strut 30 makes narrow angle 48 with expansion strut 28. First linear section 54 extends substantially collinear to joining strut 30 continuing the line of joining strut 30 into the space between expansion columns 24. The distal end of the first linear section 54 is joined to the proximal end of the second linear section 56 forming slant angle 58. Second linear section 56 extends substantially parallel to expansion struts 28 connecting at its distal end to joining strut 30 in an adjacent expansion column 24. The distal end of second linear section 56 attaches to expansion strut 28 at the point where joining strut 30 makes narrow angle 48 with expansion strut 28. Further, joining strut 30 can have a second slant angle with a width that can be the same or different from the width of the first slant angle.

FIGS. 2A and 2B show connecting struts 38 and joining struts 30 slanted relative to the longitudinal axis of stent 10, with the circumferential direction of the slanted struts alternating from column to adjacent column. Circumferential direction refers to the handedness with which the slanted struts wind about the surface of the stent 10. The circumferential direction of the slant of connecting strut first linear sections 54 in a connecting strut column 26 is opposite the circumferential direction of the slant of connecting strut first linear sections 54 in an adjacent connecting strut column 26. Similarly, the circumferential direction of the slant of joining struts 30 in an expansion column 24 is opposite the circumferential direction of the slant of joining struts 30 in an adjacent expansion column 24. Alternating circumferential slant directions of connecting struts 38 and joining struts 30 prevents axial warping of stent 10 during deliver and expansion. Other non-alternating slant direction patterns can also be used for connecting struts 38 or joining struts 30 or both.

FIG. 3A and 3B show a schematic illustration of a stent design according to the present invention in an unexpanded and expanded state respectively. The design is depicted as a flat projection, as if stent 10 were cut lengthwise parallel to its longitudinal axis and flattened out. The connecting struts 38 consist of first and second linear sections 54 and 56 forming slant angle 58 at pivot point 60. An asymmetrical cell space 40 is formed by expansion strut pairs 32, connecting struts 38 and joining struts 30. Multiple interlocking asymmetrical cell spaces 40 make up the design pattern.

As the stent is expanded, see FIG. 3B, the expansion strut pairs 32 spread apart at their open ends 36, shortening the length of expansion struts 28 along the longitudinal axis of the cylindrical stent. The longitudinal shortening of expansion struts 28 during expansion is countered by the longitudinal lengthening of connecting struts 38. The widening of slant angle 58 during expansion straightens connecting struts 38 and lengthens the distance between the coupled expansion strut pairs 32. The widening of the slant angle of connecting struts 38 substantially compensates for the longitudinal shortening of expansion struts 28. Thus, the stent has substantially constant unexpanded and expanded longitudinal lengths.

When the stent is expanded, each expansion column 24 becomes circumferentially stretched, enlarging the space between struts. The interlinking of expansion columns 24 by connecting struts 38 that have been straightened through the expansion process gives the stent 10 a high radial support strength. The entire stent 10 when expanded is unitized into a continuous chain mesh of stretched expansion columns 24 and connecting strut columns 26 forming an asymmetrical interlocking cell geometry which resists collapse both axially and radially. When the stent is expanded it has increased rigidity and fatigue tolerance.

In addition, efficient bending and straightening of connecting struts 38 at pivot points 60 allows increased longitudinal flexibility of the stent. For the stent to bend longitudinally, at least some of connecting struts 38 are forced to bend in their tangent plane. The tangent plane of a specific connecting strut 38 refers to the plane substantially tangent to the cylindrical surface of the stent at that connecting strut 38. The width of connecting struts 38 can be twice as wide as a thickness. Preferably, a one-to-one ratio is preferred. However, pivot points 60 in connecting struts 38 provide connecting struts 38 a flexible joint about which to more easily bend increasing longitudinal flexibility of the stent.

Referring to FIGS. 4A and 4B, a variation of the first embodiment of stent 10 of the present invention is shown. In this variation, stent 10 has a length 16 of 33.25 mm and an uncrimped and unexpanded circumference 88 of 5.26 mm. Fifteen expansion columns 24 are interspersed with connecting strut columns 26. Each expansion column 24 consists of twelve expansion struts 28 joined alternately at their proximal and distal ends by joining struts 30 forming six expansion strut pairs 32. Expansion struts 28 are aligned parallel to the longitudinal axis of cylindrical stent 10.

Joining struts **30** form a narrow angle **48** and a wide angle **50** with the respective expansion struts **28** of expansion strut pairs **32**. Adjacent expansion columns **24** employ alternating circumferential slant directions of joining struts **30**.

In this variation of the first embodiment, expansion strut width **62** is 0.20 mm, expansion strut length **64** is 1.51 mm, and connecting strut width **66** is 0.13 mm. Distance **68** from the outer edge of a first expansion strut **28** to the outer edge of a second adjacent expansion strut **28** in the same expansion column **24** is 0.64 mm, leaving a loop slot width **70** of 0.24 mm.

In this variation of the first embodiment, connecting struts **38** consist of a slanted first linear section **54** joined to a second linear section **56** at a slant angle **58**. First linear section **54** is slightly longer than second linear section **56** and is attached at its proximal end to an expansion strut **28** in an expansion column **24**. The attachment of the proximal end of first linear section **54** to expansion strut **28** is at the point where joining strut **30** makes narrow angle **48** with expansion strut **28**. First linear section **54** extends substantially collinear to joining strut **30** attaching at its distal end to the proximal end of second linear section **56** to form slant angle **58**. Second linear section **56** extends substantially collinear to expansion struts **28**, attaching at its distal end to an expansion strut **28** in an adjacent expansion column **24**. The attachment occurs at the point where expansion strut **28** forms narrow angle **48** with joining strut **30**. Joining struts **30** and connecting strut first linear sections **54** slant in alternating circumferential directions from column to adjacent column.

The joining of connecting struts **38** and expansion struts **28** at the point where narrow angle **48** is formed aids smooth delivery of stent **10** by streamlining the surface of the unexpanded stent and minimizing possible catching points. Bare delivery of stent **10** to the target lesion in a vessel will thus result in minimal snagging or catching as it is navigated through turns and curvatures in the vessel. Stent **10** behaves like a flexible, tubular sled as it is moved forward or backward in the vessel on the delivery catheter, sliding through tortuous vessels and over irregular bumps caused by atherosclerotic plaques inside the vessel lumen.

When fully expanded Stent **10** of FIGS. **4**A and **4**B has an internal diameter of up to 5.0 mm, while maintaining an acceptable radial strength and fatigue tolerance. The crimped stent outer diameter can be as small as 1.0 mm or less depending on the condition of the underlying delivery balloon profile; A small crimped outer diameter is especially important if stent delivery is to be attempted without predilation of the target site. When the stent is optimally crimped over the delivery balloon, the surface of the crimped stent is smooth allowing for no snagging of the stent struts during either forward or backward movement through a vessel.

FIG. **5** shows a second embodiment of the present invention in which the stent **10** in its expanded form has a gradual taper from proximal end **12** to distal end **14**. The shaded segments **72, 74, 76, 78, 80, 82** and **84** of expansion struts **28** represent regions of expansion struts **28** to be removed. Removal of the shaded segments **72, 74, 76, 78, 80, 82** and **84** provides stent **10** with a gradual taper when expanded with distal end **14** having a smaller expanded diameter than proximal end **12**. The degree of shortening of the expanded diameter of the stent **10** at a given expansion column **24** will be proportional to the length of the removed segment **72, 74, 76, 78, 80, 82**, or **84** at that expansion column **24**. In the expanded stent **10** the shortened expansion struts **28** will

have a shortened component along the circumference of the stent resulting in a shortened circumference and diameter. The tapered diameter portion can be positioned anywhere along the length of stent **10**, and the tapering can be made more or less gradual by removing appropriately larger or smaller portions of the expansion struts **28** in a given expansion column **24**.

Tapering is especially important in long stents, longer than 12 mm, since tapering of blood vessels is more pronounced over longer lengths. A long stent with a uniform stent diameter can only be matched to the target vessel diameter over a short region. If the proximal vessel size is matched with the stent diameter, the expanded distal end of the stent will be too large for the natural vessel and may cause an intimal dissection of the distal vessel by stent expansion. On the other hand, if the distal vessel size is matched with the stent diameter, the proximal end of the expanded stent will be too small to set inside the vessel lumen. It is therefore desirable to have a stent with a tapered expanded diameter.

Another way to achieve a tapered expanded stent is to change the stiffness of the stent struts, expansion struts, connecting struts or joining struts such that the stiffness of the struts varies along the length of the stent. The stiffness of the struts can be changed by altering length, width or thickness, adding additional stiffening material, using a chemical or mechanical means to alter the physical properties of the stent material, or applying one or a series of elastic elements about the stent.

Along with the use of a tapered diameter stent, a matching tapered balloon catheter would ideally be made for delivery and deployment of the tapered diameter stent. The method of using a tapered matching balloon catheter with a tapered diameter stent is within the scope of the present invention.

Using a tapered balloon to expand a non-tapered stent will also achieve a tapered expanded stent; however, since no metal is removed from the stent, the stent is tapered as a result of incomplete expansion. The stent will therefore have increased metal fraction at the tapered end resulting in increased risk of acute thrombosis. Metal fraction is the proportion of the surface of the expanded stent covered by the stent strut material. Shortening the expansion struts as shown in FIG. **5** allows for a tapered expanded stent with substantially constant metal fraction along its length.

A third embodiment of the present invention shown in FIGS. **6**A and **6**B has multiple reenforcement expansion columns **86** placed along the length of the stent **10**. The reenforcement columns **86** are placed along the stent length to provide additional localized radial strength and rigidity to stent **10**. Additional strength and rigidity are especially important at the ends of the stent to prevent deformation of the stent both during delivery and after placement. During delivery the stent ends can catch on the vessel wall possibly deforming the unexpanded stent and altering its expansion characteristics. After the stent has been placed it is important that the stent ends are rigid so that they set firmly against the vessel wall; otherwise, during a subsequent catheter procedure, the catheter or guidewire can catch on the stent ends pulling the stent away from the vessel wall and possibly damaging and/or blocking the vessel.

The specific variation of the third embodiment of stent **10** depicted in FIGS. **6**A and **6**B has a length **16** of 20.70 mm and an uncrimped and unexpanded circumference **88** of 5.26 mm. The stent **10** consists of six expansion columns **24** and three reenforcement expansion columns **86**, each consisting respectively of twelve expansion struts **28** or reenforcement

expansion struts **90**. The reenforcement expansion columns **86** are positioned one at either end, and one along the length of the stent **10**.

The expansion strut width **62** is 0.15 mm, reenforcement expansion strut width **92** is 0.20 mm, and the connecting strut width **66** is 0.10 mm. The narrow angle **48** formed by joining strut **30** and expansion strut **28** is 75 degrees, and the narrow angle **94** formed by reenforcement joining strut **96** and reenforcement expansion strut **90** is 60 degrees.

Other arrangements of reenforcement expansion columns **86**, such as providing reenforcement expansion columns **86** only on the ends of the stent, only on one end, or at multiple locations throughout the length of the stent can also be used and fall within the scope of the present invention. A taper can also be programmed into the reenforced stent **10** by shortening expansion struts **28** and reenforcement expansion struts **90** in appropriate expansion columns **24** and **86**.

A fourth embodiment of the present invention, shown in the FIGS. **7A**, **7B** and **7C**, is similar to the third embodiment but has the added feature of relief notches **98** and **100**. A relief notch is a notch where metal has been removed from a strut, usually at a joint where multiple struts are connected. Relief notches increase flexibility of a strut or joint by creating a thinned, narrow region along the strut or joint. Relief notch **98** is formed at the joint formed between first linear section **54** of connecting strut **38** and expansion strut **28**. Relief notch **100** is formed at the joint between second linear section **56** of connecting strut **38** and expansion strut **28**. The positioning of the relief notches gives added flexibility to the unexpanded stent and prevents warping at the joints when the stent is expanded. This results in a smooth surface modulation to the expanded stent frame. Relief notches can be placed at other joints and can be included in any of the previously mentioned embodiments.

FIGS. **8A** and **8B** show a side elevation view of a variation of the fifth embodiment of the stent of the present invention. In this embodiment a four piece slanted connecting strut **38** is used to couple the corner of an expansion strut pair **32** in one expansion column **24** to the joining strut **30** of a circumferentially offset expansion strut pair **32** in an adjacent expansion column **24**. The expansion struts **28**, joining struts **30**, expansion columns **24**, reenforcement expansion struts **90**, reenforcement joining struts **96**, and reenforcement expansion columns **86** are substantially similar to the fourth embodiment of FIG. **6A**. Connecting struts **38** in connecting strut columns **26**, however, have an altered geometry and connectivity, described in more detail below.

FIG. **8A** shows only the stent struts on the front half of the stent surface. The stent struts on the rear half of the stent surface are not shown. The stent appears as it would if the stent struts and space there between were opaque. FIG. **8B** shows all stent struts from both the front and rear halves. The stent appears as it would if the stent struts and the space there between were transparent.

A first variation of a fifth embodiment of the present invention, shown in FIG. **8C** consists of a stent **10** with twelve expansion columns **24**, four reenforcement expansion columns **86**, and fifteen connecting strut columns **26**. In this variation, the stent **10** has a length **16** of 31.96 mm, and an unexpanded circumference **88** of 5.26 mm.

Connecting struts **38** shown in an enlarged view in FIG. **8G** are made up of four linear sections, a proximal end section **162**, first and second intermediate sections **164** and **166** respectively and a distal end section **168** forming three slant angles **170**, **172** and **174**. The proximal end of proximal section **162** is attached to a corner **176** of an expansion strut pair **32** of an expansion column **24**. Corner **176** is formed where joining strut **30** makes narrow angle **48** with expansion strut **28**. A second corner **178** of expansion strut **32** is formed where joining strut **30** makes wide angle **50** with expansion strut **28**. Corners **176** and **178** can have an angular shape formed by joining linear expansion struts **28** and joining struts **30**, or preferably corners **176** and **178** are rounded to remove sharp edges and provide increased flexibility. Additionally rounded corners provide stent **10** with greater expandability and reduce stress in the stent strut material at the corners in the expanded stent.

Proximal end section **162** of connecting strut **38** extends from corner **176** and is attached at its distal end to first intermediate section **164** forming slant angle **170**. First intermediate section **164** extends from proximal end section **162** such that first intermediate section **164** is parallel to expansion struts **28** and is connected at its distal end to the proximal end of second intermediate section **166** forming slant angle **172**.

Second intermediate section **166** extends in a slanted orientation relative to the longitudinal axis of stent **10**, extending both longitudinally along and circumferentially about stent **10**. Preferably, second intermediate section **166** is parallel to joining strut **30** of the circumferentially offset expansion strut pair **32** in adjacent expansion column **24**.

Second intermediate section **166** attaches at its distal end to the proximal end of distal end section **168** forming slant angle **174**. Distal end section **168** extends from second intermediate section **166** attaching at its distal end to joining strut **30** of circumferentially offset expansion strut pair **32** of adjacent expansion column **24**. The attachment is at a point intermediate corners **176** and **178**, where joining strut **30** forms narrow angle **48** and wide angle **50** respectively with expansion struts **28**.

The connection point of distal end section **168** to joining strut **30** is closer to corner **176** than corner **178**. Preferably the connection point is one to two or more expansion strut widths from corner **176**. Offsetting the connection point of distal end section **168** to joining strut **30** from corner **176** to a point intermediate corner **176** and corner **178** reduces warping of the expanded stent **10**, resulting in a smooth surface modulation and reduced risk of thrombosis. Additionally, this design provides a longer total straightened length of connecting strut **38**, which further reduces foreshortening of stent **10** during expansion.

A second variation of a fifth embodiment of the present invention, shown in an unexpanded form in FIGS. **8D**, **8E** and in an expanded form in FIG. **8F** consists of a stent **10** with six expansion columns **24**, two reenforcement expansion columns **86**, and seven connecting strut columns **26**. In this variation, the stent **10** has a length **16** of 15.04 mm, and an unexpanded circumference **88** of 5.26 mm. The stent design **10** is substantially similar to the design of the first variation of the fifth embodiment of FIG. **8C** with a reduced number of expansion columns, reenforcement expansion columns, and connecting strut columns.

FIG. **8F** illustrates a portion of the expanded stent **10** of the second variation of the fifth embodiment. After expansion of stent **10** by balloon or other means, the expansion struts **28** are spread apart circumferentially, increasing the separation at the open end **36** of expansion strut pairs **32** resulting in an increase in the circumference of the stent **10**. The spreading of the expansion struts **28** causes a longitudinal shortening of the expansion columns **24**, which is compensated by a straightening of the connecting struts **38**. During the expansion process, the slant angles **170**, **172** and

174 widen straightening the connection struts **38**, and causing an increase in the separation distance between adjacent expansion columns **24**. The asymmetrical interlocking cell geometry of the expanded stent is illustrated in FIG. **8F**.

FIGS. **9A**, **9B**, **9C**, **9D**, **9E**, **9F** and **9G** illustrate a sixth embodiment of the stent of the present invention. In this embodiment a three piece slanted connecting strut **38** is used to couple the joining strut **30** of an expansion strut pair **32** in one expansion column **24** to the joining strut **30** of a circumferentially offset expansion strut pair **32** in an adjacent expansion column **24**. The joints between segments of connecting strut **38** are curved forming a smooth rounded shape. The expansion struts **28**, joining struts **30**, expansion columns **24**, reenforcement expansion struts **90**, reenforcement joining struts **96**, and reenforcement expansion columns **86** are substantially similar to the fourth embodiment of FIG. **8A**. Connecting struts **38** in connecting strut columns **26**, however, have an altered geometry and connectivity, described in more detail below.

A first variation of a sixth embodiment of the present invention, shown in FIG. **9A**, **9B** and **9C** consists of a stent **10** with eight expansion columns **24**, three reenforcement expansion columns **86**, and ten connecting strut columns **26**. In this variation, the stent **10** has a length **16** of 20.32 mm.

Relief notches **204** are utilized at the joints between reenforcement expansion struts **90** and reenforcement joining struts **96** in the reenforcement expansion columns **86** at the stent proximal end **12** and distal end **14**. Relief notches **204** reduce the width of the joints between reenforcement expansion struts **90** and reenforcement joining struts **96**, which reduces stress in the metal at the joints during and after expansion of the stent. Relief notches **204** are particularly important at the stent ends since the stent ends are especially susceptible to warping during and after expansion. Preferably relief notches **204** reduce the joint widths, such that the joint widths are substantially the same as the thickness of stent wall **46** (see FIGS. **1B** and **1C**).

Connecting struts **38** shown in an enlarged view in FIG. **9D** are made up of three linear sections, a proximal end section **194**, an intermediate section **196** and a distal end section **198** forming two slant angles **200**, **202**. The connecting struts **38** have wide radii of curvature at the joints between connecting strut sections **194**, **196** and **198**. The shape of connecting strut **38** is thus curved or wavy rather than jagged and angular. The slant angles **200** and **202** are defined by linearly extrapolating proximal end section **194**, intermediate section **196** and distal end section **198**, as shown by the dotted lines in FIG. **9D**.

FIG. **9E** shows a variation of the connecting strut design of the sixth embodiment of the present invention. The connecting strut **38** of FIG. **9E** has smaller radii of curvature at the joints between proximal end section **194**, intermediate section **196** and distal end section **198**. Connecting strut **38** of FIG. **9E** is thus more jagged and angular than that of FIG. **9D**.

Referring to the connecting struts **38** of FIG. **9D** and **9E**, the proximal end of proximal section **194** is attached to joining strut **30** of expansion strut pair **32** intermediate corners **176** and **178**. Proximal end section **194** of connecting strut **38** extends from joining strut **30** and is attached at its distal end to intermediate section **196** forming slant angle **200**. Intermediate section **196** extends from proximal end section **194** in a slanted orientation relative to the longitudinal axis of stent **10**, extending both longitudinally along and circumferentially about stent **10**. Intermediate section **196** is preferably parallel to joining struts **30** of coupled expansion strut pairs **32**.

Intermediate section **196** is connected at its distal end to the proximal end of distal end section **198** forming slant angle **202**. Distal end section **198** extends from second intermediate section **196** attaching at its distal end to joining strut **30** of circumferentially offset expansion strut pair **32** of adjacent expansion column **24**. The attachment is at a point intermediate corners **176** and **178**, where joining strut **30** forms narrow angle **48** and wide angle **50** respectively with expansion struts **28**.

The connection point of proximal end section **194** and distal end section **198** to joining struts **30** is closer to corner **176** than corner **178**. Preferably the connection point is one to two or more expansion strut widths from corner **176**. Offsetting the connection point of distal end section **198** to joining strut **30** from corner **176** to a point intermediate corner **176** and corner **178** reduces warping of the expanded stent **10**, resulting in a smooth surface modulation and reduced risk of thrombosis. Additionally, this design provides a longer total straightened length of connecting strut **38**, which further reduces foreshortening of stent **10** during expansion.

The connecting strut **38** of the sixth embodiment has one hundred and eighty degree rotational symmetry about its center. The symmetry of the connecting strut **38** does not, however, result in a symmetrical cell space as the width of loop slots **42** connected in each cell space are different. Adjacent loop slots **42** in each expansion column have alternating narrow and wide widths, preserving the asymmetry of the cell spaces. Introduction of one or many symmetrical cell spaces can be achieved in this design e.g. by providing uniform loop slot width to loop slots in adjacent expansion columns **24** contained in the same cell space. Additionally completely non-uniform cell space patterns utilizing symmetric or asymmetric cell spaces can be achieved e.g. by providing non-uniform variations in the widths of loop slots **42**.

A second variation of a sixth embodiment of the present invention, shown in an unexpanded form in FIGS. **9F** consists of a stent **10** with six expansion columns **24**, three reenforcement expansion columns **86**, and eight connecting strut columns **26**. In this variation, the stent **10** has a length **16** of 16.00 mm, and an unexpanded circumference **88** of 5.26 mm. The stent design **10** is substantially similar to the design of the first variation of the sixth embodiment of FIGS. **9A**, **9B** and **9C** with a reduced number of expansion columns **24** and connecting strut columns **26**.

A third variation of a sixth embodiment of the present invention, shown in an unexpanded form in FIGS. **9F** consists of a stent **10** with twelve expansion columns **24**, four reenforcement expansion columns **86**, and fifteen connecting strut columns **26**. In this variation, the stent **10** has a length **16** of 30.01 mm, and an unexpanded circumference **88** of 5.26 mm. The stent design **10** is substantially similar to the design of the first variation of the sixth embodiment of FIGS. **9A**, **9B** and **9C** with an increased number of expansion columns **24** reenforcement expansion columns **86** and connecting strut columns **26**.

FIGS. **10A**, **10B**, **10C**, **10D**, **10E** and **10F** illustrate some examples of alternate connecting strut designs which can be used in any of the previously discussed embodiments. FIG. **10A** shows a rounded loop connecting strut **38** which joins two circumferentially offset expansion strut pairs **32** in adjacent expansion columns. Expansion struts **28** in each expansion strut pair **32** are joined by adjoining strut **30**. Joining struts **30** are slanted such as to form a narrow angle **48** and a wide angle **50** with the expansion struts **28** they

connect. The rounded loop connecting strut 38 connects expansion struts 28 at the point where narrow angle 48 is formed between expansion struts 28 and joining struts 30. The slopes of the rounded connecting strut 38 at its proximal end 102 and distal end 104 substantially match the slopes of thejoining struts 30 connecting the pairs of expansion struts 28. The rounded loop connecting strut 38 thus blends smoothly into the joining struts 30. Additionally the rounded loop connecting strut 38 has a first radius of curvature 106 and a second radius of curvature 108.

In the design of FIG. 10B a rounded loop connecting strut 38 joins two circumferentially offset expansion strut pairs 32 in adjacent expansion columns. Expansion struts 28 in each expansion strut pair 32 are joined by a joining strut 30. Joining struts 30 are at right angles to the expansion struts 28 they connect. The rounded loop connecting strut 38 connects to expansion struts 28 at the same point as joining struts 30. The rounded connecting strut 38 has a first radius of curvature 106 and a second radius of curvature 108 such that it connects circumferentially offset expansion strut pairs 32.

In the design of FIG. 10C connecting strut 38 joins two circumferentially offset expansion strut pairs 32 in adjacent expansion columns. Expansion struts 28 in each expansion strut pair 32 are joined by adjoining strut 30. Joining struts 30 are slanted such as to form a narrow angle 48 and a wide angle 50 with the expansion struts 28 they connect. The connecting strut 38 connects expansion struts 28 at the point where narrow angle 48 is formed between expansion strut 28 and joining strut 30.

The connecting strut 38 is made up of three linear sections 110, 112, and 114 forming two slant angles 116 and 118. The proximal end of section 110 is attached to expansion strut 28 at the point where joining strut 30 forms narrow angle 48 with expansion strut 28. Section 110 extends substantially collinear to joining strut 30 and is attached at its distal end to intermediate section 112 forming slant angle 116. Intermediate section 112 extends at an angle to section 110 such that intermediate section 112 is substantially parallel to expansion struts 28 and is connected at its distal end to the proximal end of distal section 114 forming slant angle 118. Distal section 114 extends at an angle such that it is substantially collinear to joining strut 30 of the adjacent expansion strut pair 32. Distal section 114 attaches at its distal end to expansion strut 28 of the adjacent expansion strut pair 32, at the point where joining strut 30 forms narrow angle 48 with expansion strut 28.

In the design of FIGS. 10D and 10E a connecting strut 38 joins two circumferentially offset expansion strut pairs 32 in adjacent expansion columns. Expansion struts 28 in each expansion strut pair 32 are joined by a joining strut 30. Joining struts 30 are at right angles to the expansion struts 28 they connect. The connecting strut 38 connects to expansion struts 28 at the same point as joining struts 30.

The connecting struts 38 of FIGS. 10D and 10E are made up of multiple connecting strut sections connected end to end to form a jagged connecting strut 38 with multiple slant angles, coupling expansion strut pair 32 to adjacent expansion strut pair 32. The connecting strut of FIG. 10D is made up of three connecting strut sections, a proximal section 120, an intermediate section 122 and a distal section 124 defining two slant angles 126 and 128, while the connecting strut of FIG. 10E consists of four connecting strut sections, a proximal section 130, intermediate sections 132 and 134, and a distal section 136 defining three slant angles 138, 140 and 142. In addition, connecting strut section 134 can be modified by replacing connecting strut section 136 by the dotted connecting strut section 144 to give another possible geometry of connecting struts 38.

In the design of FIGS. 10F connecting strut 38 joins two circumferentially offset expansion strut pairs 32 in adjacent expansion columns. Expansion struts 28 in each expansion strut pair 32 are joined by a joining strut 30. Joining struts 30 are slanted such as to form a narrow angle 48 and a wide angle 50 with the expansion struts 28 they connect.

Connecting strut 38 is made up of four linear sections, a proximal end section 180, first and second intermediate sections 182 and 184 respectively and a distal end section 186 forming three slant angles 188, 190 and 192. The proximal end of section 180 is attached to corner 176 at the point where joining strut 30 forms narrow angle 48 with expansion strut 28. Proximal end section 180 extends at an angle to joining strut 30 and is attached at its distal end to first intermediate section 182 forming slant angle 188. First intermediate section 182 extends at an angle to proximal end section 180 such that first intermediate section 182 is substantially parallel to expansion struts 28 and is connected at its distal end to the proximal end of second intermediate section 184 forming slant angle 190. Second intermediate section 184 is substantially longer than the first intermediate section 182. Second intermediate section 184 extends at an angle such that it is substantially collinear to joining strut 30 of the adjacent expansion strut pair 32. Second intermediate section 184 attaches at its distal end to the proximal end of distal end section 186 forming slant angle 192. Distal end section 186 extends in a slightly sloping orientation relative to expansion struts 28, attaching to corner 176 of expansion strut pair 32 where joining strut 30 forms narrow angle 48 with expansion strut 28. Relief notches 206 are formed at the joint between distal end segment 186 of connecting strut 38 and corner 176 of expansion strut pair 32 to increase flexibility of the unexpanded stent and prevent warping when the stent is expanded.

One skilled in the art will recognize that there are many possible arrangements of connecting struts and joining struts consistent with the present invention; the above examples are not intended to be an exhaustive list. In particular, it is noted that (a) connecting strut sections need not be linear but may contain one or many radii of curvature, (b) connecting strut sections may each have a different longitudinal axis, (c) the joint between connecting strut sections need not be jagged or sharp, but rather can be smooth containing one or multiple radii of curvature, and (d) relief notches may be present at any of the strut joints.

The stent of the present invention is ideally suited for application in coronary vessels although versatility in the stent design allows for applications in non-coronary vessels, the aorta, and nonvascular tubular body organs.

Typical coronary vascular stents have expanded diameters that range from 2.5 to 5.0 mm. However, a stent with high radial strength and fatigue tolerance that expands to a 5.0 mm diameter may have unacceptably high stent metal fraction when used in smaller diameter vessels. If the stent metal fraction is high, the chances of acute thrombosis and restenosis potential will increase. Even with the same metal fraction a smaller caliber vessel is more likely than a larger one to have a high rate of thrombosis. It is, therefore, preferred to have at least two different categories of stents for coronary application, for example, small vessels stents for use in vessels with diameters from 2.5 mm to 3.0 mm, and large vessel stents for use in vessels with diameters from 3.0 mm to 5.0 mm. Thus, both small vessels and large

vessels when treated with the appropriate sized stent will contain stents of similar idealized metal fraction.

The stent of the present invention can be made using a CAM-driven laser cutting system to cut the stent pattern from a stainless steel tube. The rough-cut stent is preferably electro-polished to remove surface imperfections and sharp edges. Other methods of fabricating the stent can also be used such as EDM, photo-electric etching technology, or other methods. Any suitable material can be used for the stent including other metals and polymers so long as they provide the essential structural strength, flexibility, biocompatibility and expandability.

The stent is typically at least partially plated with a radiopaque metal, such as gold, platinum, tantalum or other suitable metal. It is preferred to plate only both ends of the stent by localized plating; however, the entire stent or other regions can also be plated. When plating both ends, one to three or more expansion columns on each end of the stent are plated to mark the ends of the stent so they can be identified under fluoroscopy during the stenting procedure. By plating the stent only at the ends, interference of the radiopaque plating material with performance characteristics or surface modulation of the stent frame is minimized. Additionally the amount of plating material required is reduced, lowering the material cost of the stent.

After plating, the stent is cleaned, typically with detergent, saline and ultrasonic means that are well-known in the art. The stents are then inspected for quality control, assembled with the delivery balloon catheter, and properly packaged, labeled, and sterilized.

Stent **10** can be marketed as stand alone or as a premounted delivery balloon catheter assembly as shown in FIG. **11**. Referring to FIG. **11**, the stent **10** is crimped over a folded balloon **146** at the distal end **148** of a delivery balloon catheter assembly **150**. The assembly **150** includes a proximal end adapter **152**, a catheter shaft **154**, a balloon channel **156**, a guidewire channel **158**, a balloon **146**, and a guidewire **160**. Balloon **146** can be tapered, curved, or both tapered and curved from a proximal end to a distal end in the expanded state. Additionally stent **10** can be non-tapered or tapered in the expanded state.

Typically the guidewire **160** is inserted into the vein or artery and advanced to the target site. The catheter shaft **154** is then forwarded over the guidewire **160** to position the stent **10** and balloon **146** into position at the target site. Once in position the balloon **146** is inflated through the balloon channel **156** to expand the stent **10** from a crimped to an expanded state. In the expanded state, the stent **10** provides the desired scaffolding support to the vessel. Once the stent **10** has been expanded, the balloon **146** is deflated and the catheter shaft **154**, balloon **146**, and guidewire **160** are withdrawn from the patient.

The stent of the present invention can be made as short as less than 10 mm in length or as long as 100 mm or more. If long stents are to be used, however, matching length or preferably slightly longer delivery catheter balloons will typically be needed to expand the stents into their deployed positions. Long stents, depending on the target vessel, may require curved long balloons, tapered long balloons or curved and tapered long balloons for deployment. Curved and/or tapered balloons which match the natural curve and taper of a blood vessel reduce stress on the blood vessel during and after stent deployment. This is especially important in many coronary applications which involve stenting in curved and tapered coronary vessels. The use of such curved and/or tapered balloons is within the scope of the present invention.

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

What is claimed is:

1. A stent in a non-expanded state, comprising:

a first expansion strut pair including a first expansion strut positioned adjacent to a second expansion strut and a joining strut of the first expansion strut pair that couples the first and second expansion struts at a distal end of the first expansion strut pair, a plurality of the first expansion strut pair forming a first expansion column;

a second expansion strut pair including a first expansion strut positioned adjacent to a second expansion strut and a joining strut of the second expansion strut pair that couples the first and second expansion struts of the second expansion strut pair at a proximal end of the second expansion strut pair, a plurality of the second expansion strut pair forming a second expansion column;

a first connecting strut including a first connecting strut proximal section, a first connecting strut distal section and a first connecting strut intermediate section, the first connecting strut proximal section being coupled to the distal end of the first expansion strut pair in the first expansion column and the first connecting strut distal section being coupled to the proximal end of the second expansion strut pair of the second expansion column, a plurality of the first connecting strut forming a first connecting strut column that couples the first expansion column to the second expansion column, the first connecting strut intermediate section being non-parallel to the first connecting strut proximal and distal sections, wherein the first expansion strut of the first expansion strut pair in the first expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column.

2. The stent of claim **1**, wherein a spacing distance between the first expansion strut pair and an adjacent first expansion strut pair in the first expansion column are the same.

3. The stent of claim **1**, wherein a spacing distance between the second expansion strut pair and an adjacent second expansion strut pair in the second expansion column are different.

4. The stent of claim **1**, wherein a spacing distance between the first expansion strut pair and an adjacent first expansion strut pair in the first expansion column, and a spacing distance between the second expansion strut pair and an adjacent second expansion strut pair in the second expansion column are the same.

5. The stent of claim **1**, wherein a spacing distance between the first expansion strut pair and an adjacent first expansion strut pair in the first expansion column, and a spacing distance between the second expansion strut pair and an adjacent second expansion strut pair in the second expansion column are different.

6. The stent of claim **1**, wherein a first radius of curvature is formed where the first connecting strut proximal section is coupled to the first connecting strut intermediate section.

7. The stent of claim **1**, wherein a second radius of curvature is formed where the first connecting strut distal section is coupled to the first connecting strut intermediate section.

8. The stent of claim 1, wherein a first radius of curvature is formed where the first connecting strut proximal section is coupled to the first connecting strut intermediate section and a second radius of curvature is formed where the first connecting strut distal section is coupled to the first connecting strut intermediate section.

9. The stent of claim 1, wherein a first slant angle is formed where the first connecting strut proximal section is coupled to the first connecting strut intermediate section.

10. The stent of claim 1, wherein a second slant angle is formed where the first connecting strut distal section is coupled to the first connecting strut intermediate section.

11. The stent of claim 1, wherein a first slant angle is formed where the first connecting strut proximal section is coupled to the first connecting strut intermediate section and a second slant angle is formed where the first connecting strut distal section is coupled to the first connecting strut intermediate section.

12. The stent of claim 1, wherein the stent further includes a radiopaque marker.

13. The stent of claim 1, wherein the stent includes an electroplated material for radiopaque observation under fluoroscopy.

14. The stent of claim 1, wherein a proximal end and a distal end of the stent are at least partially radiopaque electroplated.

15. The stent of claim 1, wherein a ratio of a number of expansion struts in an expansion strut column to a number of connecting struts in a connecting strut column is 2 to 1.

16. The stent of claim 1, wherein the stent includes m first and second expansion columns, n expansion struts per column and n (m-1)/2 connecting struts.

17. The stent of claim 1, wherein the first and second expansion columns are each unbroken, continuous structures.

18. The stent of claim 1, further comprising:

a reenforcement expansion column made of a plurality of reenforcement expansion struts, wherein each reenforcement expansion strut has a width that is greater than a width of an expansion strut in the first or second expansion columns.

19. The stent of claim 18, wherein the reenforcement expansion column includes a plurality of relief notches.

20. The stent of claim 1, wherein the stent has a proximal end with a first reenforcement expansion column and a distal end with a second reenforcement expansion column.

21. The stent of claim 20, wherein the first and second reenforcement expansion columns each include a plurality of relief notches.

22. The stent of claim 20, further comprising:

a third reenforcement expansion column intermediate the stent proximal end and the stent distal end.

23. A stent in a non-expanded state, comprising:

a first expansion column formed of a plurality of first expansion column strut pairs, a first expansion strut pair including a first expansion strut adjacent to a second expansion strut and a first joining strut that couples the first and second expansion struts at a proximal end of the first expansion strut pair, a second expansion strut pair including a third expansion strut adjacent to the second expansion strut and a second joining strut that couples the second and third expansion struts at a distal end of the second expansion strut pair, a third expansion strut pair including a fourth expansion strut adjacent to the third expansion strut and a third joining strut that couples the third and fourth expansion struts at a proximal end of the third expansion strut pair, a fourth expansion strut pair including a fifth expansion strut adjacent to the fourth expansion strut and a fourth joining strut that couples the fourth and fifth expansion struts at a distal end of the fourth expansion strut pair, a first expansion strut pair first corner formed where the first joining strut is coupled to the first expansion strut, and a first expansion strut pair second corner formed where the first joining strut is coupled to the second expansion strut, and a second expansion strut pair first corner formed where the second joining strut is coupled to the second expansion strut, and a second expansion strut pair second corner formed where the second joining strut is coupled to the third expansion strut, and a third expansion strut pair first corner formed where the third joining strut is coupled to the third expansion strut, and a third expansion strut pair second corner formed where the third joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair first corner formed where the fourth joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair second corner formed where the fourth joining strut is coupled to the fifth expansion strut;

a second expansion column formed of a plurality of second expansion column strut pairs, a first expansion strut pair including a first expansion strut adjacent to a second expansion strut and a first joining strut that couples the first and second expansion struts at a proximal end of the first expansion strut pair, a second expansion strut pair including a third expansion strut adjacent to the second expansion strut and a second joining strut that couples the second and third expansion struts at a distal end of the second expansion strut pair, a third expansion strut pair including a fourth expansion strut adjacent to the third expansion strut and a third joining strut that couples the third and fourth expansion struts at a proximal end of the third expansion strut pair, a fourth expansion strut pair including a fifth expansion strut adjacent to the fourth expansion strut and a fourth joining strut that couples the fourth and fifth expansion struts at a distal end of the fourth expansion strut pair, a first expansion strut pair first corner formed where the first joining strut is coupled to the first expansion strut, and a first expansion strut pair second corner formed where the first joining strut is coupled to the second expansion strut, and a second expansion strut pair first corner formed where the second joining strut is coupled to the second expansion strut, and a second expansion strut pair second corner formed where the second joining strut is coupled to the third expansion strut, and a third expansion strut pair first corner formed where the third joining strut is coupled to the third expansion strut, and a third expansion strut pair second corner formed where the third joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair first corner formed where the fourth joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair second corner formed where the fourth joining strut is coupled to the fifth expansion strut; and

a first connecting strut column formed of a plurality of first connecting struts, each connecting strut of the first connecting strut column including a connecting strut proximal section, a connecting strut distal section and a connecting strut intermediate section, a first connecting strut proximal section is coupled to the joining strut of the second expansion strut pair of the first expansion

strut column, and a first connecting strut distal section is coupled to the joining strut of the first expansion strut pair of the second expansion strut column, and a second connecting strut proximal section is coupled to the joining strut of the fourth expansion strut pair of the first expansion strut column, and a second connecting strut distal section is coupled to the joining strut of the third expansion strut pair of the second expansion strut column, the first connecting strut intermediate section being non-parallel to the first connecting strut proximal and distal sections wherein the first expansion strut of the first expansion strut pair in the first expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column.

24. The stent of claim **23**, wherein the stent includes a proximal expansion column, a distal expansion column, a plurality of connecting struts positioned between the proximal and distal expansion columns, and a plurality of expansion columns positioned between the proximal and distal expansion columns, each expansion column being made of a plurality of juxtapositioned proximal and distal looped slots.

25. The stent of claim **23**, wherein the first expansion column, the second expansion column, and the first connecting strut column form a plurality of geometric cells.

26. The stent of claim **25**, wherein at least a portion of the plurality are asymmetrical geometric cells.

27. The stent of claim **23**, wherein the first expansion column, the second expansion column, and the first connecting strut column form a plurality of cells and at least a portion of the plurality of cells form non-uniform cell space patterns.

28. The stent of claim **23**, wherein the first expansion strut column, the second expansion strut column and the first connecting strut column form a plurality of geometric configurations and at least a portion of the plurality form asymmetrical geometric configurations.

29. The stent of claim **23**, wherein the first expansion strut column, the second expansion strut column and the first connecting strut column form a plurality of geometric configurations and at least a portion of the plurality form symmetrical geometric configurations.

30. The stent of claim **23**, wherein the first connecting strut proximal section is coupled to the joining strut of the second expansion strut pair of the first expansion strut column, and the first connecting strut distal section is coupled to the first corner of the first expansion strut pair of the second expansion strut column, and the second connecting strut proximal section is coupled to the joining strut of the fourth expansion strut pair of the first expansion strut column, and the second connecting strut distal section is coupled to the first corner of the third expansion strut pair of the second expansion strut column.

31. The stent of claim **23**, wherein the first connecting strut proximal section is coupled to the joining strut of the second expansion strut pair of the first expansion strut column, and the first connecting strut distal section is coupled to the second corner of the first expansion strut pair of the second expansion strut column, and the second connecting strut proximal section is coupled to the joining strut of the fourth expansion strut pair of the first expansion strut column, and the second connecting strut distal section is coupled to the second corner of the third expansion strut pair of the second expansion strut column.

32. The stent of claim **23**, wherein the first connecting strut proximal section is coupled to the first corner of the

second expansion strut pair of the first expansion strut column, and the first connecting strut distal section is coupled to the joining strut of the first expansion strut pair of the second expansion strut column, and the second connecting strut proximal section is coupled to the first corner of the fourth expansion strut pair of the first expansion strut column, and the second connecting strut distal section is coupled to the joining strut of the third expansion strut pair of the second expansion strut column.

33. The stent of claim **23**, wherein the first connecting strut proximal section is coupled to the second corner of the second expansion strut pair of the first expansion strut column, and the first connecting strut distal section is coupled to the joining strut of the first expansion strut pair of the second expansion strut column, and the second connecting strut proximal section is coupled to the second corner of the fourth expansion strut pair of the first expansion strut column, and the second connecting strut distal section is coupled to the joining strut of the third expansion strut pair of the second expansion strut column.

34. The stent of claim **23**, wherein the first connecting strut proximal section is coupled to the first corner of the second expansion strut pair of the first expansion strut column, and the first connecting strut distal section is coupled to the first corner of the first expansion strut pair of the second expansion strut column, and the second connecting strut proximal section is coupled to the first corner of the fourth expansion strut pair of the first expansion strut column, and the second connecting strut distal section is coupled to the first corner of the third expansion strut pair of the second expansion strut column.

35. The stent of claim **23**, wherein the first connecting strut proximal section is coupled to the first corner of the second expansion strut pair of the first expansion strut column, and the first connecting strut distal section is coupled to the second corner of the first expansion strut pair of the second expansion strut column, and the second connecting strut proximal section is coupled to the first corner of the fourth expansion strut pair of the first expansion strut column, and the second connecting strut distal section is coupled to the second corner of the third expansion strut pair of the second expansion strut column.

36. The stent of claim **24**, wherein the first connecting strut proximal section is coupled to the second corner of the second expansion strut pair of the first expansion strut column, and the first connecting strut distal section is coupled to the first corner of the first expansion strut pair of the second expansion strut column, and the second connecting strut proximal section is coupled to the second corner of the fourth expansion strut pair of the first expansion strut column, and the second connecting strut distal section is coupled to the first corner of the third expansion strut pair of the second expansion strut column.

37. The stent of claim **23**, wherein the first connecting strut proximal section is coupled to the second corner of the second expansion strut pair of the first expansion strut column, and the first connecting strut distal section is coupled to the second corner of the first expansion strut pair of the second expansion strut column, and the second connecting strut proximal section is coupled to the second corner of the fourth expansion strut pair of the first expansion strut column, and the second connecting strut distal section is coupled to the second corner of the third expansion strut pair of the second expansion strut column.

38. The stent of claim **23**, wherein the first column expansion strut pairs define first column loop slots, and the second column expansion strut pairs define second column loop slots.

39. The stent of claim 38, wherein the first column loop slots are parallel to the second column loop slots.

40. The stent of claim 38, wherein the first column loop slots are not parallel to the second column loop slots.

41. The stent of claim 38, wherein the first column loop slots are longitudinally offset from the second column loop slots.

42. The stent of claim 38, wherein the first column loop slots are non-collinear to the second column loop slots.

43. The stent of claim 38, wherein the first column loop slots are collinear with the second column loop slots.

44. The stent of claim 38, wherein a width of first column loop slots is the same as a width of second column loop slots.

45. The stent of claim 38, wherein a width of the first column loop slots is different than a width of the second column loop slots.

46. The stent of claim 38, wherein a shape of the first column loop slots is different than a shape of the second column loop slots.

47. The stent of claim 38, wherein a shape of the first column loop slots is the same as a shape of the second column loop slots.

48. The stent of claim 38, wherein a shape of a first column loop slot of the first expansion column is different from a shape of an adjacent first column loop slot of the first expansion column.

49. The stent of claim 38, wherein a shape of a first column loop slot of the first expansion column is the same as a shape of an adjacent first column loop slot of the first expansion column.

50. The stent of claim 38, wherein a width of a first column loop slot of the first expansion column is different from a width of an adjacent first column loop slot of the first expansion column.

51. The stent of claim 38, wherein a width of a first column loop slot of the first expansion column is the same as a width of an adjacent first column loop slot of the first expansion column.

52. The stent of claim 23, wherein each connecting strut proximal section has a substantially linear geometry.

53. The stent of claim 52, wherein each connecting strut distal section has a substantially linear geometry.

54. The stent of claim 53, wherein each connecting strut intermediate section has a substantially linear geometry.

55. The stent of claim 23, wherein a ratio of a number of expansion struts in an expansion strut column to a number of connecting struts in a connecting strut column is 2 to 1.

56. The stent of claim 23, wherein the stent includes m first and second expansion columns, n connecting struts per column and n (m-1)/2 connecting struts.

57. The stent of claim 23, wherein the first and second expansion columns are each unbroken, continuous column structures.

58. The stent of claim 23, wherein one of the first or second expansion column is a broken column structure.

59. The stent of claim 23, further comprising:

a plurality of first expansion columns;

a plurality of second expansion columns; and

a plurality of first connecting strut columns, each first connecting strut column coupling a first expansion column to a second expansion column.

60. The stent of claim 59, wherein a plurality of first expansion columns, second expansion columns and first connecting strut columns form a continuous a chain mesh strut frame pattern.

61. The stent of claim 59, wherein the plurality of first expansion columns, the plurality of second expansion columns and the plurality of first connecting strut columns form an elongated structure.

62. The stent of claim 23, further comprising:

a reenforcement expansion column made of a plurality of reenforcement expansion struts, wherein each reenforcement expansion strut has a width that is greater than a width of an expansion strut in the first or second expansion columns.

63. The stent of claim 23, wherein the stent has a proximal end with a first reenforcement expansion column and a distal end with a second reenforcement expansion column.

64. The stent of claim 23, wherein the stent has a reenforcement expansion column between a proximal end and a distal end of the stent.

65. The stent of claim 23, further comprising:

a third expansion column formed of a plurality of third expansion column strut pairs, a first expansion strut pair including a first expansion strut adjacent to a second expansion strut and a first joining strut that couples the first and second expansion struts at a proximal end of the first expansion strut pair, a second expansion strut pair including a third expansion strut adjacent to the second expansion strut and a second joining strut that couples the second and third expansion struts at a distal end of the second expansion strut pair, a third expansion strut pair including a fourth expansion strut adjacent to the third expansion strut and a third joining strut that couples the third and fourth expansion struts at a proximal end of the third expansion strut pair, a fourth expansion strut pair including a fifth expansion strut adjacent to the fourth expansion strut and a fourth joining strut that couples the fourth and fifth expansion struts at a distal end of the fourth expansion strut pair, a first expansion strut pair first corner formed where the first joining strut is coupled to the first expansion strut, and a first expansion strut pair second corner formed where the first joining strut is coupled to the second expansion strut, and a second expansion strut pair first corner formed where the second joining strut is coupled to the second expansion strut, and a second expansion strut pair second corner formed where the second joining strut is coupled to the third expansion strut, and a third expansion strut pair first corner formed where the third joining strut is coupled to the third expansion strut, and a third expansion strut pair second corner formed where the third joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair first corner formed where the fourth joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair second corner formed where the fourth joining strut is coupled to the fifth expansion strut; and

a second connecting strut column formed of a plurality of second connecting struts, each connecting strut of the second connecting strut column including a connecting strut proximal section, a connecting strut distal section and a connecting strut intermediate section, a first connecting strut proximal section is coupled to the joining strut of the second expansion strut pair of the second expansion strut column, and a first connecting strut distal section is coupled to the joining strut of the first expansion strut pair of the third expansion strut column, and a second connecting strut proximal section is coupled to the joining strut of the fourth expansion strut pair of the second expansion strut column, and a second connecting strut distal section is coupled to the joining strut of the third expansion strut pair of the third expansion strut column.

66. The stent of claim **65**, wherein the first expansion strut of the first expansion strut pair in the second expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the third expansion column.

67. The stent of claim **65**, wherein the first expansion column, the second expansion column, and the first connecting strut column form a first plurality of geometric cells, and the second expansion column, the third expansion column and the second connecting strut column form a second plurality of geometric cells.

68. The stent of claim **68**, wherein at least a portion of the first plurality of geometric cells and at least a portion of the second plurality of geometric cells form asymmetric cells.

69. The stent of claim **67**, wherein at least a portion of the first plurality of geometric cells and at least a portion of the second plurality of geometric cells are symmetric cells.

70. The stent of claim **67**, wherein each geometric cell of the first plurality includes a proximal looped slot and a distal looped slot, and each geometric cell of the second plurality includes a proximal looped slot and a distal looped slot.

71. The stent of claim **70**, wherein each distal looped slot of a cell of the first plurality is juxtapositioned to a corresponding proximal looped slot of a cell of the second plurality.

72. The stent of claim **65**, wherein the stent includes a proximal expansion column, a distal expansion column, a plurality of connecting struts positioned between the proximal and distal expansion columns, and a plurality of expansion columns positioned between the proximal and distal expansion columns, each expansion column being made of a plurality of juxtapositioned proximal and distal looped slots.

73. The stent of claim **23**, wherein a width of the first connecting strut is equal to or less than a width of the first expansion strut of the first or second expansion columns.

74. The stent of claim **23**, wherein a width of a connecting strut of the first connecting strut column is larger than a width of a first expansion strut of the first or second expansion columns.

75. The stent of claim **23**, wherein a width of the second expansion strut of the first or second expansion columns is substantially the same as the width of the first expansion strut of the first or second expansion columns.

76. The stent of claim **23**, wherein the stent has a tapered diameter in an expanded state.

77. The stent of claim **23**, wherein the stent has a tapered geometry extending from a proximal end to a distal end in an expanded state.

78. The stent of claim **23**, wherein the stent is configured to be positioned at an exterior of an expandable balloon.

79. The stent assembly of claim **78**, wherein the balloon is curved extending from a proximal end and a distal end in an expanded state.

80. The stent assembly of claim **79**, wherein the balloon is tapered in an expanded state and the stent has a non-tapered geometry in an expanded state.

81. The stent assembly of claim **79**, wherein the balloon and the stent are both tapered in an expanded state.

82. The stent assembly of claim **79**, wherein the stent is non-tapered in an expanded state.

83. The stent assembly of claim **79**, wherein the stent is tapered in an expanded state.

84. The stent of claim **79**, wherein the stent in an expanded state is non-tapered, and the balloon is tapered and curved in an expanded state.

85. The stent of claim **79**, wherein the stent is tapered in an expanded state, and the balloon is tapered and curved in an expanded state.

* * * * *

EXHIBIT B

60/017484

Class	Subclass

ISSUE CLASSIFICATION

[redacted]

PROVISIONAL APPLICATION NUMBER

60/017484

SERIAL NUMBER	FILING DATE	CLASS	SUBCLASS	GROUP ART UNIT	EXAMINER
60/017,484 PROVISIONAL	04/26/96				

APPLICANTS

G. DAVID JANG, REDLANDS, CA.

CONTIN[illegible]****************
VERIFIED [illegible]

FOR[illegible]*******
VE[illegible]

[illegible] GRANTED 06/10/96

[illegible]	AS FILED	STATE OR COUNTRY	SHEETS DRWGS.	TOTAL CLAIMS	INDEP. CLAIMS	FILING FEE RECEIVED	ATTORNEY'S DOCKET NO.
						$150.00	[illegible]

ADDRESS

G. DAVID JANG
30725 [illegible]
REDLANDS, CA [illegible]

TITLE

INT[illegible] SERIALLY INTER-LINKED FRAME

U.S. DEPT. OF COMM./PAT. & TM—PTO-436L (Rev.12-94)

Form PTO-1625
(Rev. 5/95)

(FACE)

PATENT APPLICATION

60017484

APPROVED FOR LICENSE

JUN 0 3

INITIALS

CONTENTS

[redacted]

(FRONT)

POSITION		ID NO.	DATE
CLASSIFIER		10	6-3-96
EXAMINER		507	6-10-96
TYPIST		[illegible]	6-13-96
VERIFIER		319	6-11-96
CORPS CORR.			
SPEC. HAND			
FILE MAINT			
DRAFTING			

(LEFT INSIDE)

MAIL ROOM APR 30 1996

60/017484

PROVISIONAL PATENT APPLICATION COVER SHEET

ASSISTANT COMMISSIONER OF PATENTS
BOX PROVISIONAL
WASHINGTON, DC 20231

Dear Sir:

Enclosed for filing is a provisional patent application entitled: Intravascular Stent of Parallel-to-Serially Inter-linked Frame Pattern. This application includes 25 pages of text and eight (n=8) sheets of drawing.

The inventors of this application are:

Inventor 1
Name: G. David Jang, MD
Address: 30725 Eastbern Lane
Redlands, CA 92374 CA
Citizen of: U.S.A.

Inventor 2
Name: __________
Address: __________
Citizen of: __________

Inventor 3
Name: __________
Address: __________
Citizen of: __________

Please address correspondence to:
Name: __________
Address: __________

A check in the amount of $ 150, payable to Commissioner of Patents and Trademarks, is enclosed. [$75 for small entity; $150 for large entity.]

Respectfully submitted,

G. David Jang

PATENT APPLICATION SERIAL NO. 60/017484

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

010 WJ 05/28/96 60017484
1 114 150.00 CK

PTO-1556
(5/87)

7drawings

150-114- Alphonsio
60/017484

MAIL ROOM APR 1996

PROVISIONAL U.S.PATENT APPLICATION

Title: Intravascular Stent of Parallel-to-Serially Inter-linked Frame Pattern

Inventor: G. David Jang, MD
30725 Eastbern Lane
Redlands, CA 92374
Tel (909) 794-1803
Fax (909) 794-1938

Application Date: April 26, 1996

Background of the Invention

Angioplasty, either coronary or general vascular, has advanced to be the most effective means of re-vascularization, as an alternative to the conventional bypass graft surgery. First became a practical tool in early 1980's for clinical practice in the coronary artery, the balloon catheter dependent angioplasty has consistently proven to be the most reliable and practical interventional procedure. Other ancillary technologies such as lasers, directional or rotational atherectomies was proven to be either limited effectiveness or to be dependent on the balloon angioplasty to complete the intended procedure.

The restenosis phenomenon following balloon based angioplasty has been the most obvious drawback of the procedure, especially in the coronary artery system. Many different regimens designed to combat the restenosis phenomenon has not been very successful, including means of lasers, directional or rotational atherectomy. Contrary to these observations, intravascular stenting in recent years began to show noticeable reduction of the restenosis rate following the angioplasty procedures. The intravascular

stent depends on the balloon angioplasty for pre-dilatation, stent deployment and post-stent dilatation.

The intravascular stent works like a scaffolding of the inside lumen of a vessel when the vessel is pre-dilated with balloon, and the stent is properly deployed inside the vessel. The scaffolding effect of the stent would result as following: (a) prevents the common elastic recoil of the vessel wall which has been dilated with balloon catheter, (b) eliminates the residual stenosis that is commonly seen after a balloon angioplasty is completed, (c) the stented vessel segment has often shown to maintain slightly wider vessel lumen than the native unobstructed vessel segments proximal to and distal to the stented segment, and (d) the latest clinical series do indicate that the stented vessel has lower restenosis rate. During the follow up period after a vascular intervention, the restenosis rate of the stented vessels has significantly lower than any other means used in angioplasty, including some early drugs tried and the other technologies mentioned earlier.

There are other benefits of vessel stenting. A good example, specifically in the coronary artery, is the potential reduction of the emergency bypass surgery arising from angioplasty procedures. Stenting has proven to be effective in some cases of impending closure of the vessel during angioplasty; thus, circumventing emergency bypass surgery. Stenting could also control and stabilize an unstable local intimal tear of a vessel caused by a normal conduct of an angioplasty procedure. In some cases, an incomplete or less than optimal dilatation of a vessel lesion with balloon angioplasty can successfully be opened up with stent implant.

Stenting practice, especially in coronary arteries, had a wide swinging anti-coagulation problems in the early days,

but better and easier to use regimen are being introduced into practice continuously. Hospital stay following stent implant is getting shorter and outpatient anticoagulation techniques are becoming simpler.

Although stents are very effective and beneficial once they are properly deployed and implanted, the first generation stents are sometimes very difficult to use due to the factors such as: (a) columnar rigidity of the un-expanded stent and lack of flexibility to turn around the corners in the guiding catheter as well as the native vessels that generally have tendency to be tortuous, and (b) flimsiness of the un-expanded stent frame which may be damaged or distorted during delivery to the vessel lesion site because of the tortuosity and resistance caused by the guiding catheter and the native vessel. Some of the other drawbacks of the current generation stents are: (1) a significant fore-shortening of the stent when stent is expanded and deployed, and (2) limitation of the stent length due to the design limitations of the current generation stents. Especially, the lack of flexibility of a stent during delivery phase of the procedure is problematic. When the stent is longer in length, the difficulty of using these stents compounds. Making the (pre-expansion) stent flexible for easy delivery, while making it structurally strong and free of distortion to the stent frame after deployment, as well as capacity to allow longer stents, are the new challenges in designing the future generation stents.

The stent of present invention addresses these limitations and flaws of the first generation stents. The new stents of present invention are designed to be more flexible and easy for delivery; while retaining the desired structural soundness and endurance when deployed. Furthermore, the new stents of present invention have the

programming ability to make the stent to be tapered, to have set the stent diameter for different size vessel, and to give freedom of the stent length. These key features of the stent of present invention would set the new standards for the future coronary and vascular stent designs.

Summary of the Invention

A stent is a thin walled metal frame in a cylindrical shape designed to be implanted inside a vessel wall by means of delivering on a catheter based delivery vehicle. A stent is in pre-expansion form with relatively low profile during delivery, but transformed into an expanded high profile form when deployed. The expanded stent is to open the inside lumen of the target segment of a vessel (or a duct) by expansion of stent frame from inside so that the lumen created by the expanded stent would be same as the original native vessel lumen size or slightly larger. When the stent is properly delivered and deployed, it is generally implanted permanently.

A stent has to have the expandability provision built into its structural design. Without this essential expandability of the stent frame, the desired effect of a stent can not be expected. The expandability, plus the necessity of very thin stent wall and the frame strength requirement, are the reasons why the stents are popularly made of a metal, especially the first generation vascular stents. But any new material, including polymers, can be used in the future if such material could suffice the essential structural and expandability requirements of a stent are met.

There are a number of different means by which to expand the stent once it is delivered inside the target lesion of a vessel. Following are some of the potential

methods of expanding stents inside a vessel: (a) self-expansion by the metal memory of the stent frame when released from trapping means, (b) balloon mounted stents that would be passively expanded into place by inflation of the delivery balloon, (c) a combination of the two methods mentioned above, or (d) possibly by other method not yet introduced or publicly known.

The first generation stents that are available in the market today have a number of limitations and drawbacks. Some of them are structurally flimsy and lacks the scaffolding strength against a resistant of recoiling forces of a vessel where the stent is deployed. Some of them has enough structural strength to withstand the vessel resistance or recoil but is very rigid and non-flexible for tracking a generally tortuous and sometimes resistant natural vessel during delivery phase of a procedure. Some of these stents works well once delivered and deployed properly, but very difficult to deliver to the vessel because the stent in its pre-expansion mode is too stiff and very inflexible for negotiating the naturally tortuous vessels. Also some of these first generation stents have tendency to foreshorten the length of the stent when it is deployed and expanded. This foreshortening of a stent is a negative feature and has its origin traced in the flaws of stent frame design.

The new stents of present invention are intended to overcome these negative characteristics that are commonly seen in the first generation stents, and to maximally enhance the desirable features that are lacking in these first generation stents. The present invention of parallel-to-serially inter-linked stent has many features that are not available in the first generation stents. The stent of present invention is designed to be: (1) flexible in the delivery mode, (2) no snagging of the stent strut when it is

moved forward or backward bare inside the vessel lesion, (3) to minimize foreshortening of the stent when it is expanded, (4) to have continuous chain mesh of inter-linking struts which will separate individual cells from each other but the entire stent frame is unitized, (5) no inherent limitations for stent length, (6) provision to program tapering of the diameter in longer length stents, (7) ideal application in coronary vessels, (8) versatile applications in the non-coronary peripheral vessels, the aorta, and in the non-vascular tubular body organs, (9) for easy manufacturing, (10) consistent quality control, (11) ability to use more than one kind of construction material, (12) an ability to market the stent as stand-alone or pre-mounted on a stent delivery vehicle catheter, 13) to maximize its delivery with bare stent, and 14) to allow, in rare occasion, to deliver and deploy the stent without pre-dilatation. Furthermore, versatility of the frame design of present invention would allow programming of the following stent definitions: a) overall metal surface fraction, b) wall thickness, c) strut width, d) open space between struts, e) number of horizontal strut (or cell) cycles over the circumference of the stent, f) stent diameters, g) gradual tapering of the stent in longer lengths, and more.

The frame pattern of the present invention is seamless with horizontally paralleling strut cycles arranged in columns over the circumferential surface of the stent in the pre-expansion mode; when it is viewed from the side elevation of the stent horizontally placed with proximal and distal ends pointing west and east directions respectively. These paralleling horizontal struts are in pairs of two, which are serially connected to a single strut that has a slanted angle and, in turn, the single slant-angled strut is again serially connected to a pair of next column of paralleling horizontal struts one split level above or below. This slant-angled serially connecting strut can be

arranged in an alternating spatial orientation; resulting in the slant-angled serial strut connecting the horizontal paralleling struts one level above or below the originating level of the serial strut. When this parallel-serial struts are connected in the alternating fashion as the figures illustrate in this application, open spaced cells are created by parallel-serial inter-linking strut network. Each open cell, as can be seen in the figures later, is bordered by two pairs of paralleling strut units connected by one serial strut above and bellow. Both sides of the open cells are closed by the column of parallel struts. At both proximal and distal ends of the stent, the parallel struts will have blind loops, as illustrated in the figures, instead of being connected to a serially connecting slant-angled strut. When this unitized, parallel-to-serially linked, stent is expanded by the deployment means such as balloon, the entire stent will expand in a uniform fashion; transforming the pre-expansion mode of the stent into a cross-linked continuous and seamless mesh of the stent struts.

The overall length of the parallel-serial link stent of present invention would be determined by the number of parallel strut columns and horizontal width of the pre-expansion parallel strut column, and the horizontal width of the serial struts between the parallel strut columns. Likewise, the maximum rate of stent expansion would be determined by the number of the parallel strut (or cell) cycles around the circumference (or in the parallel strut columns) of the pre-expansion mode of the stent, and the relative horizontal length of the individual parallel strut units.

The parallel-serial inter-linked stent of present invention is designed as a balloon-expandable stent. However, any other stent expanding mechanism beside the

balloon also can be utilized if such device is suitable. The stent of present invention will have a distinctly different expanded frame pattern than the pre-expansion pattern of the stent. The virtue of transformation from the pre-expansion to post-expansion modes of a stent would make it an ideal or a mediocre stent. The parallel-serial inter-link stent has an ideal transformation from one mode to the next; making it an ideal balloon expandable stent.

Although this parallel-serial inter-link stent design is for balloon expansion, this same parallel-serial inter-linked frame pattern can be used in a self-expanding stent application, using different stent material that is suitable for self-expanding stent.

This parallel-serial link stent of present invention has many ideal features desired in a vascular, especially coronary, stent. Following are further amplification of the specific features that can be found in the stent of present invention:

(a) The stent of present invention is designed to be <u>flexible</u> and <u>malleable</u> in its pre-expansion form, so that the stent can be delivered to a target lesion, even if the vessel segment leading to the target lesion is tortuous. The flexibility of the stent of present invention owes to the unique parallel-to-serially inter-connecting strut and frame design. A pair of two paralleling struts are inter-linked to a single slant-angled strut that is connected to the next unit of a pair of paralleling struts one level above or below the previous pair of paralleling strut unit, repeating in an alternating fashion, along its entire length of the stent and over its circumference of the stent. Thus, for every two paralleling struts, there is one slant-angled serial inter-connecting strut. This specially designed serial strut inter-connecting two split level parallel strut

units is the key to the flexibility of this stent of present invention. Furthermore, the slant-angled serial link strut is made slightly narrower than the more dominant parallel struts, without compromising the structural integrity of the whole stent, to elicit additional suppleness of the slanted struts when the stent moves around the turns and curves of the natural blood vessel. This feature also adds to the overall flexibility of the stent. Another factor for smoothness of the stent movement during stent delivery is the angle at which the either end of the parallel strut units are joined with the serial inter-connecting struts in a continuous and alternating fashion.

(b) Although the pre-expanded mode of the stent of present invention is malleable and flexible, the stent frame network transforms into a quite rigid tubular cage in the expanded mode. There remains a very little flexibility after the stent is fully expanded. This characteristic of transforming itself from a flexible frame to a rigid frame by expansion increases the radial strength of the stent and would elevate the fatigue tolerance of the implanted stent in the long run.

(c) If the stent of present invention is delivered bare to the target lesion in a vessel, there will be no snagging or catching of the stent struts as the stent is navigated through the turns and curvatures of a natural vessel. This critical feature is provided by the very design characteristics of the parallel-serial inter-linking struts of the stent frame. The entire stent frame would behave like a flexible, tubular sled as it is moved forward or backward with the delivery balloon catheter vehicle. The serial inter-linking strut and the joining angles of the parallel struts to the serial strut are set such a way that either forward or backward movements of the stent would slide over the irregular bumps created by

the atherosclerotic plaques inside the vessel lumen, or by the tortuous vessel walls.

(d) This stent design of present invention would minimize the foreshortening phenomenon of the stent expansion commonly seen in the first generation vascular stents. One reason for minimized foreshortening of the stent of present invention is because of the fact that the parallel strut cell cycles expand individually along its own axis of expansion over the enlarging circumference by inflation of stent expanding means, in unison with other parallel strut cells in the stent. Another reason is that the slant-angled serial struts would straighten its length between the two expanding parallel strut columns. The open cell space between the stent struts would expand rapidly as the parallel struts realign into a zigzag pattern over the enlarging circumference, while maintaining the horizontal width of the parallel strut column minimally narrowed. These structural and metallurgic factors contribute to the minimal foreshortening nature of the parallel-serial stent of present invention.

(e) The stent of present invention would have a high radial strength for its given stent metal fraction. When the stent is expanded, the parallel struts transforms into a zigzag shape maintaining its own individual closed circle around the circumference of the expanded stent. Because there is no break in the zigzag shaped strut circle of individual parallel strut column, it would maintain a maximum radial resistance for a given metal fraction of the stent. Another factor that contributes to the high radial strength is that these individual zigzag shaped circular rings are inter-linked with adjacent zigzag rings by the serial struts along the horizontal length of the stent, adding the lateral stability. When the entire stent is unitized into a continuous chain mesh of the parallel and serial struts in this fashion, the rigidity

of the frame is increased as the expanded stent is set inside the vessel wall. When the parallel-serial link stent is deployed and the rigidity of the frame is maximized by stent expansion inside a vessel, the fatigue tolerance of the stent would rise to the highest level.

(f) Within reason, the parallel-serial link stent has no inherent limitations with respect to the potential length of the total stent in a single unit. This stent of present invention can be made into <u>any reasonable length</u> without sacrificing the flexibility and malleability of the stent frame during delivery movements.

(g) The <u>expansion rate</u> of this stent of present invention is programmable. This parallel-serial link stent has a high possible expansion rate. For general purpose parallel-serial link stent made for medium size vessels, this stent could be made to expand up to 4.5mm to 5.0 mm in ID (internal diameter) from the crimped, balloon mounted OD (outer diameter) of 1.0 to 1.2 mm. This level of expansion from a crimped OD of 1.0 mm is about the theoretical expansion limit; while retaining an acceptable radial strength and fatigue tolerance of a stent.

(h) <u>Low stent profile</u> of the delivery mode is another positive feature of the parallel-serial link stent. With a well made and low profile stent delivery balloon catheter, this stent of present invention can achieve an OD of 1.0 mm when the stent is crimped on the underlying folded expansion balloon. Low profile stent (in delivery mode) is very desirable when stenting without pre-dilatation is contemplated. Bare stent delivery would also be desirable in a scenario of no pre-dilation stenting. The parallel-serial stent has an excellent bare stenting qualities. Crimping quality of the parallel-serial inter-link stent over a folded delivery balloon is extraordinarily good.

(i) The parallel-serial link stent of present invention is ideal for coronary application. However, this stent of present invention is also well suited in stent applications in Aorta, Carotids, Peripheral and Non-vascular areas.

(j) Furthermore, the parallel-serial link stent design of present invention could also be use in a self-expanding stent format. Combination of memory metal and malleable metal could make this stent design of present invention into a initially self-expanding and partially balloon-expandable stent format.

The balloon-expandable parallel-serial link stent of present invention can be made with stainless steel or any other medically acceptable metal with sufficient radial strength and high fatigue tolerance. Titanium, Nitnol, Tantalum or any other suitable metal or alloy thereof has been used to make vascular stents. Nitnol, tantalum alloy, tensile steel or other suitable metal can be used to make this stent of present invention a self-expanding stent. This design of parallel-serial inter-link stent of present invention can also be made of a suitable polymer, if such material become available.

The parallel-serial link stent of present invention made of stainless steel or other agreeable metal can be gold-plated on both or either end of the stent for fluoroscopic marker purpose. Further, entire stent surface of present invention can be gold-plated with the conventional electro-plating technique. When the entire stent is gold-plated, the stent would be better visualized under fluoroscopy. Moreover, a gold-plated stent may interact differently with the complex molecular, cellular and growth factors in the stented vascular structure than that would be with the stainless steel or other metal surface. A gold-plated stent may favorably interact with the

bio-molecular and cellular factors to reduce the adverse reactions of platelet aggregation, growth of fibroblasts, intimal hyperplasia or even restenosis phenomenon.

The parallel-serial link stent of present invention can be made out of metal tube, sheet metal or metal wire. If a plastic material has the similar characteristics as the metallic material, such material could potentially be used for making the stent. Combination of metal and polymer material certainly could be used making such stent, if the materials are compatible and the meets the engineering, fabrication, biological and structural fatigue tolerance requirements.

More detailed description of making the parallel-serial link sent of present invention using a stainless steel tube will be discussed. For a coronary stent that could be used for the coronary diameter between 2.5 to 7.0 mm can be made of a stainless steel tube of 1.6-1.8 mm in OD (outer diameter) and wall thickness of 0.002-0.005 inches. First the scale drawing of the stent design of present invention is drawn into a CAD (e.g.- DXF file) system which in turn would be translated into a CAM program. The CAM program then would be used to drive a precision laser cutting system. Such CAM driven laser cutting system would cut the stent pattern originally drawn in the CAD DXF file out of the stainless steel tube mentioned above. When the steel tube is cut into a stent of the present invention, the rough cut stent is electro-polished to lift the stained and discolored metal surfaces, as well as to smooth out the sharp edges of the stent struts. After this process, the stent is thoroughly cleaned with detergent, saline and ultrasonic means that are well known in the industry, then the stents are individually inspected for quality control before packaging and sterilizing.

The parallel-serial stent of present invention is very flexible in its delivery mode. For delivery into a coronary artery, for example, the stent would be mounted on the properly folded balloon skin of the stent delivery vehicle catheter. Then the stent is crimped down evenly over the balloon underneath. When this stent of preset invention with the specified dimensions in the Figure 5 is properly crimped on the delivery balloon catheter in the pre-expansion mode, the outer diameter of the stent mounted on the balloon would become as little as 1.0mm or less depending on the folded profile of the stent carrier balloon. The parallel-serial link stent of present invention that is illustrated in the Figure 5 has a maximum expanded inner diameter of 5.0 mm, indicating an excellent expansion rate. When the same stent is expanded to 4.0 mm or larger in diameter, the stent metal fraction would become approximately 10% or less. Although the stent in its pre-expansion mode is highly flexible, the expanded stent of present invention would became quite rigid, increasing its fatigue tolerance in vivo. The rigidity of the expanded mode of the stent of present invention is largely due to the unique parallel-serial link design of the stent struts and their changed configuration after the expansion.

The stent of present invention does not have any inherent limitations to the length. The stent can be made as short as less than 10mm in length or as long as 100 mm or more. If the long stents are produced, the matching delivery catheter balloons also needed to expand the long stents in deployed position.

With regards to the expanded diameter of the stent of present invention, single (diameter size) stent could cover from 2.5 mm to 5.0 mm in diameter. However, if a stent that would expand to 5.0 mm in size, but still has necessary radial strength and high fatigue tolerance, would have an

unacceptably high stent metal fraction in low diameter expansion, in such case as in small size vessel with 2.5 mm in diameter. If the stent metal fraction is high, the chances for acute thrombosis and restenosis potential would increase rapidly. Even with a same given metal fraction, smaller caliber vessel is more likely to have higher rate of thrombosis than the large caliber vessel. It would make sense, therefore, the smaller vessel would require a specially programmed stent to suit the requirements of the small vessel stenting environment. Specifically, the coronary vessel between 2.5 mm to 3.0 mm in diameter would require a different diameter size stent with a lower stent metal fraction, that are different from the medium to large sized coronary vessels. It would be desirable to have at least two separate stents of size category for coronary stenting, to compensate the pitfalls of the single size does it all approach of coronary stenting. Likewise, it may be further desirable to have a separate category stent size for the large caliber vessels such as the vessels with 4.5 mm or larger in diameter, even in coronary field alone.

With the stent features of present invention, programming the stents of different size category can easily and effectively be achieved. For small caliber vessels, the horizontal strut (or cell) cycles are reduced (e.g.- 4-5 cycles) and the strut width are narrowed down (e.g.- .004-.005" with wall thickness of .002"), to reduce the metal fraction while providing the necessary radial strength and fatigue tolerance that would match with the smaller vessels. Similarly, the larger vessels would require increase in horizontal strut cycles with or without increase in the strut width or wall thickness of the stent, to induce a higher stent expansion and to meet the required radial strength and necessary fatigue tolerance. All these different categories of stents would have similar flexibility characteristics in the pre-expansion and

delivery mode, although the largest size stent category would behave more robust than the smallest size stent category.

Brief Description of Figures

Figure 1 - The side elevation (1-a), the longitudinal section (1-c) and the cross-section (1-b) of the stent of present invention .

Figure 2 - The schematic drawing of the pre-expansion mode (2-a) and the post-expansion mode (2-b) of the stent of present invention.

Figure 3 - The cut open view of the full frame strut pattern of the stent of present invention.

Figure 4 - A magnified CAD drawn cut open details in scale of the stent strut pattern of present invention.

Figure 5 - A CAD drawn in scale of the cut open view of the stent strut pattern (5-a) and a close up dimensions of the stent frame struts (5-b) of present invention.

Figure 6 - Alternative rounded loop serial inter-connecting strut designs: a rounded loop serial inter-link strut with slanted joining with parallel struts (6-a) and a rounded loop serial inter-link strut with perpendicular joining with the parallel struts (6-b) of the stents of present invention.

Figure 7 - Alternative serial inter-link strut designs of present invention: a trapezoid shaped serial inter-link strut with slanted joining with the parallel struts (7-a), a trapezoid shaped serial inter-link strut with perpendicular joining with the parallel struts (7-b), and a multiple angle serial inter-link strut design variations (7-c) of the stents of present invention.

Figure 8 - Illustration of how to program tapering of the distal diameter of the parallel-serial stent.

Detailed Description of Figures

Figure 1 - The side elevation of the pre-expansion mode of the parallel-to-serially inter-linked stent 10 of present invention as seen in Figure (1-a). The stent 10 has the proximal end 12 and the distal end 14; defining the total length 16 of the stent 10. There is the proximal opening 26 and the distal opening 28, connecting to the inner lumen 32 of the stent 10. The entire stent is a single piece, without any seams or welding joints. The frame of the stent 10 is consist of the inter-connected frame struts 18 and 20, forming a continuous mesh of frame struts 18 and 20. When seen on the side elevation of Figure (1-a) with the proximal end 12 pointing to the left and the distal end 14 to the right, the parallel struts 18 are arranged horizontally in a paralleling pattern and the serial struts 20 are arranged partially horizontal and partially diagonal. For every two parallel struts 18, there is one serial strut 20. The serial strut 20 joins a pair of two parallel struts 18 in a slanted angle on both ends of the serial strut 20; thus, a single serial strut 20 is connecting four parallel struts 18. The parallel struts 18 and the serial struts 20 are seamlessly and continuously joined together to form the entire stent 10. Note that the serial strut 20 connects the two separate pairs of parallel struts 18 which are located at a level split from each other. The serial strut 20 is basically a slanted "L" or a "J" shape reversed. The horizontal segment 19 of the serial strut 20 is an extension of the joining of the horizontally oriented parallel strut 18 at one end and the slanted segment 21 of the serial strut 20 is the extension of the slanted joining segment that connects the two parallel struts 18 on the other end. However, the serial strut 20, including both the horizontal segment 19 and the slanted segment 21, has a slightly narrower strut width than the parallel struts 18. The orientation of the linking pattern of the serial strut 20 is alternating as can be seen in the Figure (1-a) in a regularly recurring fashion. These

specific features of the serial struts 20 and how they inter-connect with the parallel struts 18 is the key to the flexibility of the stent 10 during the delivery phase of the stenting; with the stent 10 is mounted over the delivery balloon catheter. These unique parallel-to-serially inter-linking strut design of the present invention also makes the stent 10 to become structurally rigid when it is expanded inside a blood vessel, increasing the fatigue tolerance of the stent 10 in vivo.

Inter-linking of the parallel struts 18 by the serial struts 20 repeats continuously lengthwise from the proximal end 12 to the distal end 14. Likewise, this inter-linking pattern of parallel struts 18 and serial struts 20 also continues around the circumference 36 of the stent 10. When the parallel struts 18 and the serial struts 20 are continuously inter-linked, without interruption, along the entire length 16 and around the circumference 36 of the stent 10, the entire stent 10 becomes a mesh of struts 18 and 20 in a cylindrical shape. As the parallel and the serial struts 18 and 20 make up the mesh of a cylindrical structure, there would be the cells 22 of open space 24 bordered by the parallel struts 18 and serial struts 20, and the individual cells 22 would be separated from each other by the parallel and serial struts 18 and 20.

The cross-section shown in Figure(1-b) illustrates the outer diameter 40 and the radius 38 of the stent 10. The circumference 36 is consists of the thin stent wall 34.

The Figure (1-c) is a longitudinal section of the stent 10. The proximal end 12 and the distal end 14 defines the total length 16 of the cylindrical stent 10. The stent lumen 32 is surrounded by the stent frame struts 30 around the circumference of a thin-wall 34, which is consists of stent frame struts 30. The stent frame strut 30 is either a parallel strut 18 or a serial strut 20.

Figure 2 - Schematic illustrations of the pre-expansion mode and the post-expansion mode are presented in Figures (2-a) and (2-b) respectively. In this schematic illustration of Figure (2-a) the serial strut 20 is joining the parallel strut 18 in a perpendicular angle, rather than at a slanted angle as illustrated in Figure 1. This variation is within the scope of the present invention. The borders of the enclosed cells 22 of open space 24 is well shown in this drawing. This schematic drawing of Figure (2-a) shows only one half circumference of the cut-open stent 10 of the present invention.

The Figure (2-b) is a schematic illustration of how the stent 10 of pre-expansion mode shown in Figure (2-a) would appear when the stent 10 of Figure (2-a) is expanded. As can be seen, the circumferential dimension of the expanded stent 44 is markedly increased with expansion of the stent 10. However, the length of the expanded stent 44 is minimally decreased. In the expanded stent 44, the open cell space is markedly increased, making the stent frame metal (strut) fraction to a very low level. Note how the configuration of the parallel struts has changed in the expanded stent 44. The parallel struts 18 now has an open zigzag pattern extending over the central axis of expansion 66 and along the circumference 37. This circumferencial extension of the parallel struts 18 is the key to the expansion rate of the stent 10 of present invention.

Figure 3 - This is an illustration of the cut-open 2-dimentional view 46 of the <u>pre-expansion mode</u> of the parallel-serial link stent 10 of Figure 1. From the proximal end 12 to the distal end 14 the parallel struts 18 are inter-connected by the serial struts 20 continuously. A pair of two parallel struts 18 at one level are serially inter-connected to the next pair of two parallel struts at another split level by a single serial strut 20; along the entire stent length 16 and around the full stent circumference 37.

The slanted joining angles 53 and the split level interconnection of the parallel struts 18 by the serial struts 20 that has a reversed slanted "L" shape are clearly illustrated in this figure. The proximal end loop 48 and the distal end loop 50 are also clearly illustrated. The open space cells 22 are also well shown. The strut width of the serial strut 20 is slightly narrower than the parallel struts 18. Although there is no scale marks in this illustration of Figure 3, this illustration is an approximation of a 20 mm length coronary stent which will expand up to 4.5 mm in diameter.

Figure 4 - This is a close up view of the stent frame design of the un-expanded parallel-serial link stent 10 of Figure 3. This illustration was drawn by a 2-dimentional CAD program that can be translated into a laser cutting CAM program. The dimensions of this cut open view 46 of the stent 10 is in an exact proportional scale. The ratio of width between parallel struts 18 and the serial struts 20 are real. At the right end of the Figure 4, one can easily recognize the distal loops 50 of the parallel struts 18 at the distal end 14. Similarly, there would be the proximal loops 48 at the proximal end 12 on the left end of this cut-open view 46 of the stent 10, although not shown in this cut-off illustration. The cut open points 43 are clearly marked. The vertical line drawn and marked as 66 over the parallel struts 18 column is the central axis of expansion of the parallel struts 18 over which the line 66 is drawn. When the stent is expanded, these group of 12 parallel struts 18 in the column would expand over the circumference along the central axis 66 of expansion. All the columns of parallel struts 18 would simultaneously expand along the central axes 66 of expansion of their own, as the stent expanding balloon is inflated underneath the pre-expansion stent which is crimped over the stent expanding balloon. The serial struts 20 would also react to the balloon inflation.

The length of the serial strut 20 would increase minimally as the angled serial strut 20 straightens out proportional to the level of circumferential lengthening of the parallel struts 18 as the stent 10 is expanded as a unit by the inflating stent balloon. The higher the expansion, the more straightening of the serial struts 20. The cell space 22 and open space 24 are well defined in this Figure 4 of the cut-open 2-dimentional view 46 of the parallel-serial stent 10 of present invention. Each of these open cells 22 are separated from each other by the continuous chain mesh of the inter-linked parallel 18 and serial 20 struts.

The serial struts 20 are connecting a pair of parallel struts 18 from one level to another pair of parallel struts 18 at a split level. Furthermore, the serial struts 20-a at one column are in an upright position, but at the next column the serial struts 20-b are in an upside down position. This alternating column orientation of the serial struts 20 continues lengthwise from one end to the other of the stent 10. This recurring pattern of orientation of the serial struts 20 would give a certain flexibility and trackability characteristics to the crimped delivery mode of the stent 10 of present invention. However, the connecting pattern of serial strut 20 can be modified in a numerous different manners. One example is that either the 20-a serial strut connecting pattern or the 20-b serial strut connecting pattern can be used through out the entire stent 10. Such serial strut connecting pattern would give a slightly different flexibility or trackability characteristics to the stent 10. Likewise, vertical or horizontal mirror image orientation of the serial strut 20 connecting pattern of these examples also can be utilized. In fact, the crossed image (of lens) orientation of the above described serial strut 20 connecting patterns also can be used. All these variations of the connecting patterns and orientations of the serial struts 20 are within the scope of the present invention.

Figure 5 - This is a production quality 2-dimentional CAD drawing of the cut-open view of the stent 10 of present invention in the pre-expansion and pre-crimped mode. The Figure (5-a) is a parallel-serial inter-link stent 10 with approximately 33 mm in length. This illustration is in real scale proportion. When expanded fully, its ID (internal diameter) can be expanded up to 5.0 mm. If the conditions of the delivery balloon profile is right, the crimped stent OD (outer diameter) could become as low as 1.0 mm or less. Because of the innovative inter-linking pattern and angle between the parallel 18 and serial 20 struts, this stent 10 shown in this Figure (5-a) would have excellent flexibility and trackability over the guidewire, when this stent 10 is optimally crimped over the delivery balloon underneath. When the stent 10 is optimally crimped over the delivery balloon, the surface of the low profile crimped stent 10 would be smooth without any snagging of the stent struts, either for forward or backward movement. The optimally crimped stent 10 of present invention has a surface configuration that is equivalent to a tubular sled; enabling the stent 10 of present invention to move smoothly forward or backward through the inner lumen of the target blood vessel.

The figure (5-b) is also a scale drawing by a 2-dimentional CAD system. The dimensions of the parallel 18 and serial 20 struts are clearly specified and matches with the scale of the Figure (5-a) above.

Figure 6 - Alternative serial inter-link strut 20 designs are illustrated in these drawings. Figure (6-a) has a rounded loop configuration 52 of the horizontal segment 19 of the serial inter-connecting strut 20. The slanted segment 21 of the serial connecting strut 20 is smoothly blended into the rounded loop segment 52 of the serial inter-link strut 20. In Figure (6-a), the serial inter-link strut 20 joins with adjacent parallel struts 18 at a slanted angle 53

on both sides, that is flush with slanted segment of the serial strut 20.

Figure (6-b) illustrates yet another variation of the serial inter-connecting pattern. This figure is identical to the figure (6-a) in all respect except for that the joining angle 54 of the serial strut 20 with the parallel struts 18 is perpendicular (square angled) to the parallel struts 18 on both sides.

Figure 7 - This figure further illustrates another set of design variations of the serial inter-link strut 20. In Figure (7-a), the horizontal segment 19 of the serial strut 20 is raised to form a top of a trapezoidal configuration 56. The slanted segment 21 is unchanged from the original serial inter-link strut 20. The joining angle 53 of the serial strut 20 with the parallel struts 18 on both sides is slanted. By raising of the horizontal segment to form a trapezoidal configuration 56 also necessitated extending a short connecting arm 57 between the serial strut 20 and the parallel strut 18-b.

Figure (7-b) has the same trapezoidal configuration of the horizontal part 56 and the slanted segment 21 of the serial strut 20. However, the joining angles 54 of the serial strut 20 are perpendicular (or square angled) to the parallel struts 18 on both sides. There is another small detail in this figure; the distal end 62 of the slanted segment 21 of the serial strut 20 is angled to flush with the horizontal orientation of the parallel strut 18-a. The dotted lines in the Figure (7-b) illustrates another configuration of joining of the serial strut 20 with the parallel strut 18-a, similar to the previous alternative examples of the stent 10 of present invention. The connecting arm 57 between the serial strut 20 and the parallel strut 18-b is unchanged from Figure (7-a).

Figure (7-c) illustrates two more variations of the serial inter-link strut 20 configurations. The serial strut

20 further evolves from Figure (7-b) into other variations in this illustration. The horizontal portion 58 of the serial strut 20 has an asymmetrical configuration with a vertically oriented segment before joining with the parallel strut 18-a. The terminal end of the vertical segment 59 can have a square-angled arm 62, a slanted arm (dotted lines) 64 or even a rounded arm, which is not illustrated here, in joining with the parallel strut 18-a.

Figure 8 - This illustration shows how to program a diameter tapering of the distal end of the stent 10. An artery or vein in the vascular system in vivo does not have uniform diameter through out its length. A natural vessel is gradually tapered from the proximal origin to the distal end. If the stent 10 has a long length (e.g.- 20-40 mm), the stent diameter is equal through out its length, and the proximal vessel size is matched with the stent diameter, the expanded distal end of the stent would be too large for the natural vessel and may cause an intimal dissection of the distal vessel by stent expansion. On the other hand, if the distal vessel size is matched with the stent diameter, the proximal end of the expanded stent would be too small to set inside the vessel lumen. Toward preventing these adverse phenomenon, the stent 10 of present invention was designed with a special feature. The distal end of this stent 10 can be programmed for gradual tapering of the distal end of the stent to match with the naturally tapering anatomy of a vessel in vivo.

Figure 9 is a modification of the earlier Figure 3. There are ten (n=10) columns of the parallel struts arranged horizontally from left (the proximal end 12) to right (the distal end 14). The parallel strut columns are marked with alphabets in sequence from left to right; the first column at the proximal end 12 as "A" and the last column at the distal end 14 as "J". There is a band of shaded segments cutting through vertically over the "J" column of the

parallel struts. These shaded areas are for elimination from the horizontal length of the parallel struts in order to effect a desired amount of reduction in diameter of the parallel struts in the "J" column. A proportional reduction of the horizontal length of the parallel struts in the "J" column would result in a proportional reduction of the maximum expanded diameter of the distal end of the stent 10 corresponding the "J" column. In order to make the tapering gradual in the distal end of the stent 10 of Figure 8, the preceding columns (e.g.- G, H and I) of the parallel struts are also reduced progressively in reverse order. In other words, the amount of the reducing areas 65 in each column of parallel struts are tapered in a reverse order from the distal column "J" to the more proximal columns "I", "H" and "G". The resulting effect would be that the remaining horizontal length of the parallel struts are gradually more shortened from the column "G" to column "J", with the diameter at the distal end (i.e.- column "J") set with the targeted and planed diameter. The bracketed length 66 can be programmed shorter or longer to meet the tapering requirements. The gradual tapering of the diameter can begin much more proximal than the illustration in this Figure 8. For example, the tapering could begin from column "C" or "D" all the way to Column "J". Such a tapering would be much more gradual.

Along with use of a tapered diameter stent, a matching tapered balloon catheter would ideally be made for delivery and deployment of the tapered diameter stent. Method of using a tapered matching balloon catheter with a tapered diameter stent 10 is within the scope of the present invention.

EXHIBIT A

Legends for Illustrations:

10 – The stent of Parallel-Serial Link Frame Strut Pattern

12 – Proximal end

14 – Distal end

15 – Cut off point in the middle of the stent

16 – Total length of the stent

18 – Parallel frame strut

(18-a) – First parallel strut to the left (or toward the distal end of the stent 10)

(18-b) – First parallel strut to the left (or toward the proximal end of the stent 10)

19 – Horizontal segment of Serial strut

20 – Serial inter-linking strut

21 – Slanted segment of Serial strut

22 – Stent cell

24 – Open space between the stent frame struts

26 – Proximal opening

28 – Distal opening

30 – Stent frame struts

32 – Stent inner lumen

34 – Stent wall

36 – Circumference of the stent

37 – Half circumference of the stent

38 – Radius of the stent

40 – Diameter (outer) of the stent

42 – Cut open frame view of the one half circumference of the stent; Pre-expansion mode

43 – Cut open point of the stent strut

44 – Cut open frame view of the one half circumference of the stent; Post-expansion mode

46 – Cut open frame view of a full stent

48 – Proximal end loop
50 – Distal end loop
51 – Central axis of expansion
52 – Rounded loop serial inter-link strut
53 – Angled (or slanted) joining with parallel struts
54 – Perpendicular (or square angle) joining with parallel struts
56 – Trapezoidal shape serial inter-link strut
57 – Joining arm of the trapezoidal serial strut with parallel strut 18-b
58 – Asymmetrical trapezoidal shape serial inter-link strut
60 – Square angle anchoring point of the serial inter-link strut
62 – Horizontal extension arm at anchoring point of the serial inter-link strut
64 – Slanted arm at anchoring point of the serial inter-link strut
65 – Area (or length) of the parallel struts to be eliminated to shorten the horizontal length of the parallel struts – to effect a tapered diameter of the distal end of the stent 10
66 – Length to be shortened for distal diameter tapering

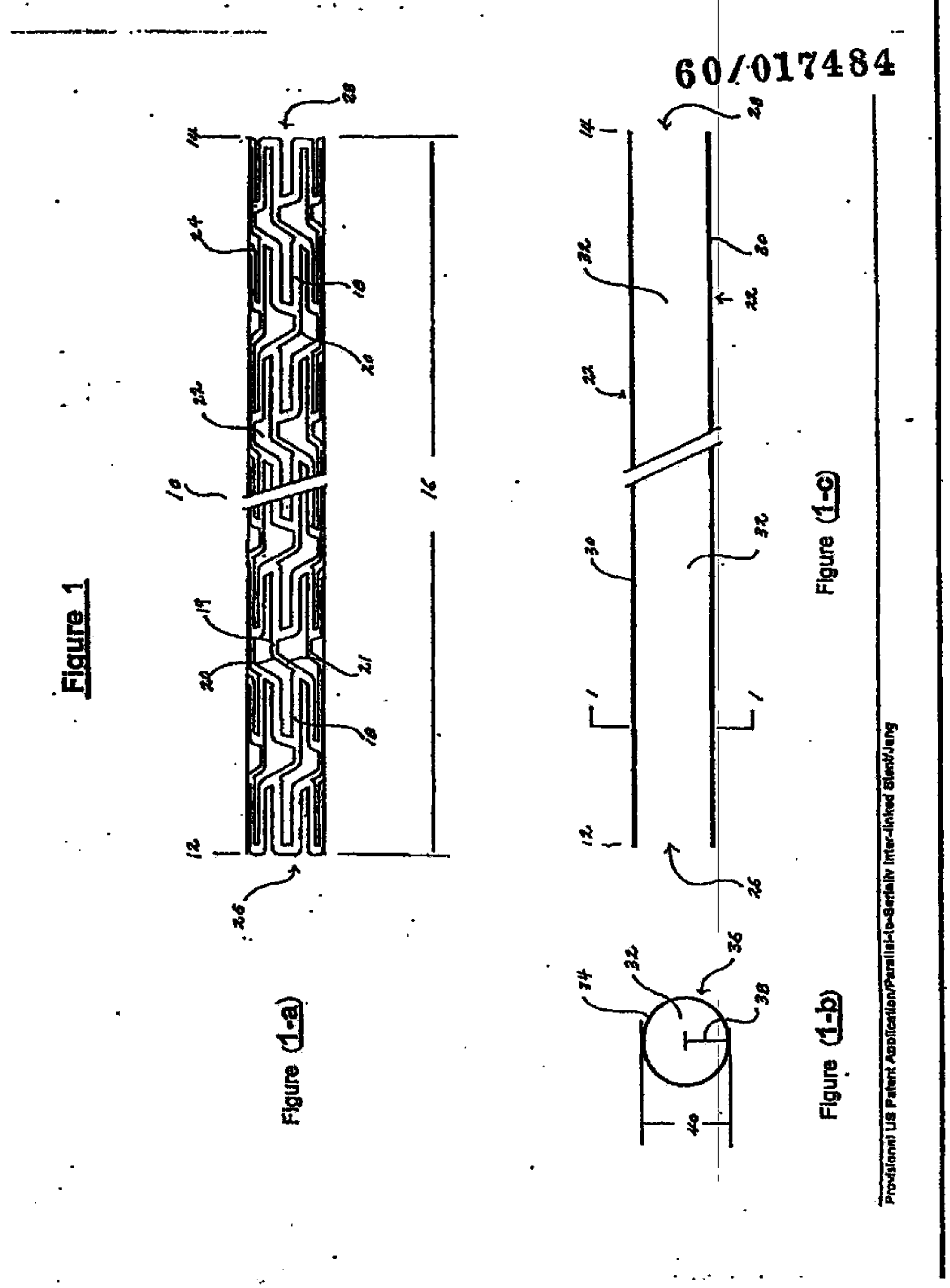


Figure 1

Figure (1-a)

Figure (1-b)

Figure (1-c)

60/017484

Provisional US Patent Application/Parallel-to-Serially Inter-linked Stack/Jang

Figure 2

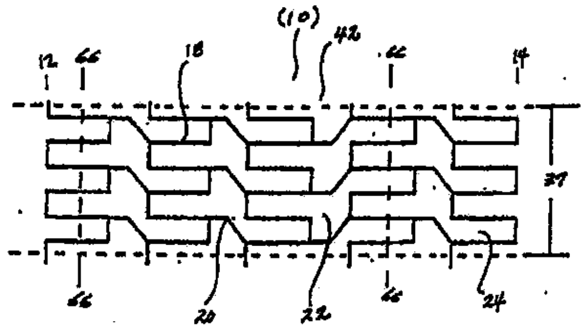


Figure (2-a)

60/017484

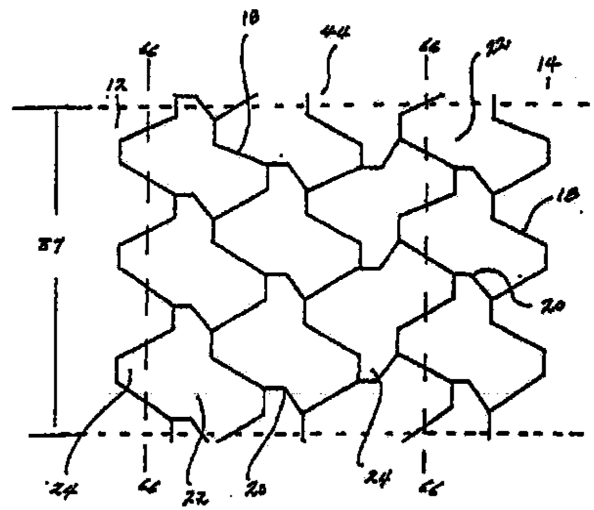


Figure (2-b)